

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

IN RE : ETHICON, INC.,)	
PELVIC REPAIR SYSTEM)	Master File
PRODUCTS LIABILITY)	No.
LITIGATION)	2:12-MD-02327
)	
_____)	
)	
THIS DOCUMENT RELATES TO)	
PLAINTIFF:)	
)	
Susan Guinn Case No.)	
2:12-cv-01121)	

- - -
DEPOSITION OF STANLEY ZASLAU, M.D.
THURSDAY, MARCH 17, 2016
- -

The Deposition of STANLEY ZASLAU, M.D., a
Witness herein, called by the Plaintiff, taken
pursuant to Notice of Deposition and the West
Virginia Rules of Civil Procedure, by and before
Faye Ann Lehman, a Commissioner in and for the
State of West Virginia, at The Waterfront Place
Hotel, 2 Waterfront Place, Morgantown, West
Virginia 26501, commencing at 11:30 a.m. on the day
and date above set forth.

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<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES: 2 3 On behalf of the Plaintiff: 4 Edward A. Wallace, Esquire 5 Wexler Wallace LLP 6 55 West Monroe Street, Suite 3300 7 Chicago, Illinois 60603 8 eaw@wexlerwallace.com 9 10 On behalf of the Defendants: 11 Susan M. Robinson, Esquire 12 Thomas Combs & Spann, PLLC 13 300 Summers Street, Suite 1380 14 Charleston, West Virginia 25301 15 srobinson@tcspllc.com 16 --- 17 18 INDEX 19 WITNESS PAGE 20 STANLEY ZASLAU, M.D. 21 Direct Examination by Mr. Wallace 3 22 Cross-Examination by Ms. Robinson 154 23 Redirect Examination by Mr. Wallace 162 24 EXHIBITS No. 1 Notice to take Deposition 3 No. 2 Expert Report, Guinn case 7 No. 3 Expert Report, Hendrix case 8 No. 4 C.V. and Testimony List 8 No. 5 TVT IFU ETH.MESH.05225354 - 05225385 111 No. 6 TVT IFU, 2015 123 (No Bates) No. 7 AUGS/SUFU Position Statement 131 No. 8 Email chain ETH.MESH.00301741 - 00301742 135 No. 9 Email chain ETH.MESH.01822361 - 01822363 139 No. 10 PA Consulting Group PowerPoint 141 (No Bates) ---</p>	<p style="text-align: right;">Page 4</p> <p>1 Q. Am I right that you brought a suitcase with 2 you today? 3 A. Yes. 4 Q. And what's in the suitcase? 5 A. The suitcase has medical records and 6 literature, as well as thumb drives that I've 7 reviewed in preparation. 8 Q. And why did you bring the suitcase full of 9 that material today? 10 A. So I can refer to it as necessary. 11 Q. Did you do anything in connection to a 12 request for documents from you having to do with 13 the reports that you've issued in this litigation? 14 A. Yes. 15 Q. What did you do? 16 A. I read it and reviewed them and discussed 17 them with counsel. 18 Q. And is it fair to say that you've made a 19 diligent and thorough search for any documents that 20 you've been asked to bring today? 21 A. Yes. 22 Q. Are you withholding anything? 23 A. No. 24 Q. Can you just identify more specifically</p>
<p style="text-align: right;">Page 3</p> <p>1 PROCEEDINGS 2 --- 3 STANLEY ZASLAU, M.D., 4 the witness, having been first duly sworn, was 5 examined and testified as follows: 6 (Deposition Exhibit No. 1 was marked 7 for identification.) 8 DIRECT EXAMINATION 9 BY MR. WALLACE: 10 Q. I'm going to hand you a document that's been 11 marked as Exhibit 1. Tell me if you recognize it. 12 A. I do. 13 Q. Does it have your name on it? 14 A. Yes. 15 Q. Can you state and spell your name for me. 16 A. My name is Stanley, S-T-A-N-L-E-Y, Zaslaw, 17 Z-A-S-L-A-U. 18 Q. Do you know why you're here today? 19 A. Yes. 20 Q. Why is that? 21 A. I'm being deposed by you. 22 Q. In connection with what? 23 A. In connection with claims regarding a mesh 24 and mesh-based surgeries.</p>	<p style="text-align: right;">Page 5</p> <p>1 what you've brought so we can just note it for the 2 record? 3 A. I brought articles that I've reviewed in 4 preparation from a variety of different sources. I 5 brought thumb drives with medical records and other 6 articles that were provided to me by Butler & Snow, 7 and I have brought medical records and depositions 8 that I've reviewed for this case and discussion. 9 Q. And if I understand you correctly, you were 10 asked to look at materials and then provide an 11 opinion in this case, right? 12 A. Yes. 13 Q. And if I'm correct, you've provided a -- 14 what is called a general opinion with respect to 15 the safety and efficacy of the TVT device, right? 16 A. Yes. 17 Q. But you've also reviewed medical records and 18 other information relating to two claimants, Susan 19 Guinn and Ms. Hendrix; is that right? 20 A. Yes. 21 Q. And you understand that my questions today, 22 Dr. Zaslaw, are about the general TVT opinions and 23 not those two specific claimants, right? 24 A. Yes.</p>

<p style="text-align: right;">Page 6</p> <p>1 Q. And you understand that after we're done 2 today, that someone will be asking you questions 3 about your case-specific report for Ms. Guinn, 4 right? 5 A. Yes. 6 Q. Okay. Thank you. With respect to your 7 general TVT report, it's my understanding from 8 looking at the documents or the reports that you 9 provided that your general opinion is the same -- 10 it was issued in the Guinn case and the Hendrix 11 case, but it's the same for both, right? 12 A. Yes. 13 Q. In other words, it's meant to apply to TVT 14 specifically without regard to who the plaintiff 15 might be? 16 A. Well, if it were a TVT-O case, there's more 17 material regarding TVT-O in some than others. I 18 don't believe that the reports are exact copies of 19 one another. There are sections that are similar, 20 but certainly, other relevant research for TVT-O 21 that was more recent. 22 Q. Why don't we do this, then, why don't we 23 mark both of the reports separately, just for the 24 record, and then the exhibits, as I understand</p>	<p style="text-align: right;">Page 8</p> <p>1 will be the Hendrix report. 2 (Deposition Exhibit No. 3 was marked for 3 identification.) 4 Q. Have you seen Exhibit 3 before? 5 A. Yes. 6 Q. What is it? 7 A. This is a general report for a retropubic 8 TVT, but also is case specific for the Hendrix 9 case. 10 Q. So, in other words, just so we're clear, 11 even if we're not taking the Hendrix deposition 12 today, you know that you're here by agreement to 13 give opinions on your general TVT opinion? 14 A. Yes. 15 Q. And your general TVT opinion is contained in 16 Exhibit 3? 17 A. Yes. 18 Q. Let's mark as a group exhibit your CV and 19 your testimony list as Exhibit 4. 20 (Deposition Exhibit No. 4 was marked for 21 identification.) 22 MS. ROBINSON: Did you say CV and? 23 MR. WALLACE: Testimony list. 24 MS. ROBINSON: As Exhibit 4?</p>
<p style="text-align: right;">Page 7</p> <p>1 them, are generally the same. 2 For example, your CV's the same, right? 3 A. Yes. 4 Q. Your list of testimony is the same? 5 A. Yes. 6 Q. Why don't we mark the Guinn report as 7 Exhibit 2, please. 8 (Deposition Exhibit No. 2 was marked 9 for identification.) 10 Q. Do you recognize Exhibit 2? 11 A. Yes. 12 Q. What is it? 13 A. It is the report for the Guinn case. 14 Q. And, again, at the beginning of that, it 15 has a section that also provides general opinions? 16 A. Correct. 17 Q. And if I'm correct, Ms. Guinn had a TVT-O 18 implanted? 19 A. Yes. 20 Q. But you're here to testify about the TVT 21 today, right? 22 A. Yes. 23 Q. Now, if you look at the -- we're going to 24 mark the next exhibit, and that is Exhibit 3, which</p>	<p style="text-align: right;">Page 9</p> <p>1 MR. WALLACE: Yeah. 2 BY MR. WALLACE: 3 Q. Do you recognize Group Exhibit 4? 4 A. Yes. 5 Q. What is that? 6 A. This is a testimony -- a history for the 7 last four years and my current CV. 8 Q. I notice that certain areas are blacked out. 9 Is that your doing or your counsel's doing? 10 A. Counsel's doing. 11 Q. With respect to the testimony list, please 12 take a look at it. 13 A. Um-hmm. 14 Q. It says "2014 - Edwards versus JNJ"? 15 A. Yes. 16 Q. That's a mesh case, correct? 17 A. Yes. 18 Q. And do you recall meeting Mark Mueller in 19 giving your deposition in that case? 20 A. Yes. 21 Q. Have you reviewed that transcript recently? 22 A. I have not. 23 Q. When's the last time you looked at it? 24 A. Six months ago or more.</p>

<p style="text-align: right;">Page 10</p> <p>1 Q. And why six months ago did you look at it?</p> <p>2 A. Because that's when I got it.</p> <p>3 Q. And so, since then, in connection with</p> <p>4 preparing your reports in this case, you haven't</p> <p>5 referenced it?</p> <p>6 A. I have not.</p> <p>7 Q. The Weaver versus WVUH case; what is that?</p> <p>8 A. That was a case -- a prostatectomy case, a</p> <p>9 prostate cancer case that I was involved in that I</p> <p>10 was since waived from its involvement and settled.</p> <p>11 Q. Oh, so, you were a party to that case?</p> <p>12 A. Yes.</p> <p>13 Q. And you testified in that case?</p> <p>14 A. Yes.</p> <p>15 Q. At deposition?</p> <p>16 A. At deposition only.</p> <p>17 Q. And you were later dismissed from the case?</p> <p>18 A. Yes.</p> <p>19 Q. And you didn't pay anything, did you?</p> <p>20 A. I did not pay anything.</p> <p>21 Q. The Stewart versus Bard case in 2014, what</p> <p>22 is that?</p> <p>23 A. Yes. I am the treating physician.</p> <p>24 Q. Is it a mesh case?</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. What was -- did you link the mesh to the</p> <p>2 cause of Ms. Stewart's injuries?</p> <p>3 A. I don't remember the specifics of that</p> <p>4 because it was some time ago. I'd have to go back</p> <p>5 and look to the details of it.</p> <p>6 Q. Do you recall giving testimony on behalf of</p> <p>7 Bard in that case?</p> <p>8 A. No. I was purely the treating physician,</p> <p>9 opposed by that counsel.</p> <p>10 Q. The final one on the list is Burkhart,</p> <p>11 B-U-R-K-H-A-R-T versus Life Chiropractic?</p> <p>12 A. Right.</p> <p>13 Q. What sort of testimony did you offer in that</p> <p>14 case?</p> <p>15 A. It's a treating physician and expert in a</p> <p>16 case of neurogenic bladder. It's not a mesh-based</p> <p>17 case. It's a urinary retention case, unrelated to</p> <p>18 any pelvic floor issues.</p> <p>19 Q. So you were retained by one of the parties</p> <p>20 in the case?</p> <p>21 A. As a treating physician, but also served as</p> <p>22 an expert.</p> <p>23 Q. On whose behalf?</p> <p>24 A. Patient.</p>
<p style="text-align: right;">Page 11</p> <p>1 A. Yes.</p> <p>2 Q. Is it a case that's pending in the MDL</p> <p>3 before Judge Goodwin, if you know?</p> <p>4 A. I do not believe so.</p> <p>5 Q. Do you know where it is pending?</p> <p>6 A. I do not.</p> <p>7 Q. Who, if anyone, has been dealing with you in</p> <p>8 that case?</p> <p>9 A. Matt Teague, T-E-A-G-U-E.</p> <p>10 Q. He's from Beasley Allen; do you know?</p> <p>11 A. Yes.</p> <p>12 Q. So you've had interaction with him about</p> <p>13 that case?</p> <p>14 A. Yes.</p> <p>15 Q. Did you provide a report in connection with</p> <p>16 that case?</p> <p>17 A. No.</p> <p>18 Q. But you did give testimony?</p> <p>19 A. I gave a deposition for that.</p> <p>20 Q. And did you offer opinions in that</p> <p>21 deposition?</p> <p>22 A. Whatever questions were asked of me, but I</p> <p>23 was certainly not an expert. I was a treating</p> <p>24 physician.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. And so you testified that there was a</p> <p>2 causal link between the actions of the defendant</p> <p>3 and the plaintiff's injuries?</p> <p>4 A. That's correct.</p> <p>5 Q. If I also recall, you have offered testimony</p> <p>6 in the past having to do with a case involving the</p> <p>7 Veterans Administration, right?</p> <p>8 A. Yes.</p> <p>9 Q. So you remember what I'm talking about?</p> <p>10 A. Um-hmm.</p> <p>11 Q. Can you just give a brief description of</p> <p>12 that, please?</p> <p>13 A. This was a patient who had an unrecognized</p> <p>14 ureteral injury at the time of an anterior repair.</p> <p>15 There may have been more procedures in addition to</p> <p>16 that, but she had a complex pelvic prolapse case.</p> <p>17 It was unrecognized. She was referred for</p> <p>18 treatment to our facility, for which we treated</p> <p>19 her. And it turns out her ureter was ligated</p> <p>20 during the initial surgery, and subsequently that</p> <p>21 case had been tried, lost, and then been tried</p> <p>22 several other times. I'm not sure how that all</p> <p>23 played out, but it was -- the physician worked in a</p> <p>24 facility that was a federal facility, so I don't</p>

<p style="text-align: right;">Page 14</p> <p>1 know if it was a federal case without a jury.</p> <p>2 Q. But as far as you know, the testimony that</p> <p>3 you've given in the last four years are listed in</p> <p>4 Group Exhibit 4?</p> <p>5 A. Yes.</p> <p>6 Q. And is your CV that you provided in</p> <p>7 connection with your report up to date?</p> <p>8 A. Yes.</p> <p>9 Q. How much time did you spend preparing your</p> <p>10 TVT report?</p> <p>11 A. About 30 hours.</p> <p>12 Q. Are those hours documented anywhere?</p> <p>13 A. I just keep a running list of them at the</p> <p>14 end of the month. I'm involved in multiple cases,</p> <p>15 so there's a lot of time that's spent each month</p> <p>16 in reviewing records and writing reports and</p> <p>17 opinions for a variety of things. So it's a summed</p> <p>18 opinion --</p> <p>19 Q. I'm sorry. I didn't mean to interrupt.</p> <p>20 A. It's a summed, you know, time together.</p> <p>21 Q. Do you -- based upon your answer, do you</p> <p>22 have any way to estimate the number of hours or</p> <p>23 percentage of working time that you spend each</p> <p>24 month on mesh-related matters?</p>	<p style="text-align: right;">Page 16</p> <p>1 in that -- between you and the lawyers or between</p> <p>2 you and Ethicon?</p> <p>3 A. I work with the Butler & Snow group. I</p> <p>4 don't work with anyone else or any other mesh</p> <p>5 companies, meaning, like, you know, Boston</p> <p>6 Scientific or any of those others. I do not.</p> <p>7 I've only worked exclusively with them.</p> <p>8 Q. Just to be clear, Susan is sitting next to</p> <p>9 you. You'd assume she's part of the group, right?</p> <p>10 A. Susan's part of the group.</p> <p>11 Q. Okay, very fine lawyer I might add. I just</p> <p>12 wanted to make that clear.</p> <p>13 How much time did you spend preparing for</p> <p>14 your deposition today?</p> <p>15 A. I spent probably about 20 hours of just</p> <p>16 deposition prep.</p> <p>17 Q. Over how much time?</p> <p>18 A. Over the last two to three weeks.</p> <p>19 Q. And who did you meet with, if anyone?</p> <p>20 A. I've spoken with Susan, and I've spoken with</p> <p>21 other counsel, part of Butler & Snow, part of the</p> <p>22 group.</p> <p>23 Q. Who?</p> <p>24 A. Paul Rosenblatt.</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I'd say the bulk of my free time is based on</p> <p>2 that. I don't have any other things that are going</p> <p>3 on. It doesn't mean I'm doing this every day, you</p> <p>4 know, all hours of the day, but I would estimate</p> <p>5 that I spend about two hours a day on average doing</p> <p>6 this related work.</p> <p>7 So I may spend up to 60 hours a month doing</p> <p>8 something, but it can average between ten hours a</p> <p>9 month, if things are quiet; but if there's multiple</p> <p>10 cases -- here's these three going on -- and</p> <p>11 reports, so I could spend upwards of 30 or more</p> <p>12 hours a month.</p> <p>13 Q. Are these the only two cases in which you're</p> <p>14 working on?</p> <p>15 A. These are the only cases I'm working on</p> <p>16 right now that I've written reports for, but I've</p> <p>17 reviewed many other cases that are in various other</p> <p>18 stages or processes.</p> <p>19 Q. And you've reviewed those cases for Ethicon?</p> <p>20 A. For attorneys for Ethicon.</p> <p>21 Q. At the end of the day, though, it's -- your</p> <p>22 bills are paid by them?</p> <p>23 A. Yes.</p> <p>24 Q. Do you have a retainer agreement that exists</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. Who else?</p> <p>2 A. And I spoke with an attorney, Susan Pope,</p> <p>3 for the Goodwin case.</p> <p>4 MS. ROBINSON: Guinn.</p> <p>5 A. Well, no. Susan Pope is the Goodwin case.</p> <p>6 I've been working on that as well. So you're</p> <p>7 talking about -- she knows about this as well.</p> <p>8 There's a lot of folks, as you know, that's</p> <p>9 involved in this.</p> <p>10 Q. That's right. Just so we're clear, because</p> <p>11 you talk a little fast, when you say "the Goodwin</p> <p>12 case," you're not talking about Judge Goodwin.</p> <p>13 There's another case that you're referring to that</p> <p>14 exists out there that relates to Ethicon?</p> <p>15 A. Right.</p> <p>16 Q. And the lawyer you identified as Susan Pope</p> <p>17 is connected to that case?</p> <p>18 A. Yes.</p> <p>19 Q. You're not from West Virginia, are you?</p> <p>20 A. No.</p> <p>21 Q. Where are you from?</p> <p>22 A. New York.</p> <p>23 Q. Brooklyn?</p> <p>24 A. Um-hmm.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. And prior to coming to West Virginia, you 2 were a resident in New York, right? 3 A. Yes. 4 Q. And if I'm correct, you finished your 5 residency in -- 6 A. 2000. 7 Q. In 2000? 8 A. Yes. 9 Q. And came to West Virginia in 2001 as an 10 assistant clinical professor, right? 11 A. Assistant professor, yes. 12 Q. What's that mean? 13 A. Well, I'll tell you, in between I spent a 14 year in -- achieving advanced training in 15 neurourology and voiding dysfunction in Brooklyn at 16 Long Island College Hospital as an assistant 17 attending. So essentially an additional year of 18 training, a fellowship year. And then I came for 19 an academic position at WVU as an assistant 20 professor. 21 Q. Right. An assistant attending, though, just 22 to be clear, is not a fellowship? 23 A. It is not. That's correct. But this year 24 was meant to be additional training, so additional</p>	<p style="text-align: right;">Page 20</p> <p>1 A. When you are an assistant professor, you're 2 a full member of the faculty, and so your 3 responsibility is patient care, surgery, and call 4 responsibilities. But my focus and goal was to 5 build a center for voiding and sexual dysfunction 6 for the people of West Virginia, using knowledge 7 from my additional year of training and from Mount 8 Sinai and bring that here and build something that 9 didn't exist in our state. 10 So that's when I came here, and I started 11 to build that center of excellence for the center 12 for voiding and sexual dysfunction. 13 Q. And to be clear, that had nothing to do with 14 mesh, right, between 2001 and 2004? 15 A. No. I mean, well, these were things that we 16 had done at the time, certainly. We've done mesh 17 since 1998 as a resident, but coming here to build 18 this had nothing to do with mesh. 19 Q. That's all I'm trying to make clear, that 20 the work that you did between 2001 to 2004 to try 21 and build this center that you're describing was 22 not mesh-related? 23 A. That's correct. 24 Q. And as I understand it, you became -- you</p>
<p style="text-align: right;">Page 19</p> <p>1 training in neurourology. Back at that time, there 2 were very few formal fellowships, so if you wanted 3 additional training in this area, you could be 4 employed by a hospital and focus in those areas, so 5 that's what I did for that year, and then brought 6 that knowledge to WVU the following year. 7 Q. Who recruited you? 8 A. To where? 9 Q. West Virginia. 10 A. There was an advertisement looking for 11 someone who had done the things that I do, and I 12 had contacted Dr. Stanley Kandzari, who was the 13 chief of urology at the time, and we spoke, and I 14 came to interview, and I thought it was a great 15 opportunity. 16 Q. And you've been here ever since? 17 A. Um-hmm. 18 MS. ROBINSON: Say "yes." 19 A. Yes. 20 Q. Let's go back to what your role was in 2001 21 for a moment. 22 A. Okay. 23 Q. I don't think that's clear. 24 What did you do as an assistant professor?</p>	<p style="text-align: right;">Page 21</p> <p>1 had various titles all the way up to being named as 2 a professor in 2010, right? 3 A. Yes. 4 Q. And I take it that between 2001 and 2010, 5 you received pay raises? 6 A. Yes. 7 Q. And that with the change in titles that you 8 received in those intervening years, that that's 9 typically when the pay raises occurred, right? 10 A. No. They can happen annually. You know, 11 we're salaried employees, so our salary is 12 dependent upon normative numbers that are used 13 nationally for academic professors, and so there 14 may be a raise each year. Usually it's equivalent 15 to what would be a standard of living for that 16 salary level. And the pay raise from -- actually, 17 from rank is actually very little. It's really 18 more -- the way our system is based, you can be a 19 full professor, but you're really compensated more 20 based on your clinical productivity and the 21 national norms. 22 Q. Between 2001 and 2010, would you consider 23 yourself in private practice? 24 A. No.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. What would you consider yourself working in?</p> <p>2 A. Academic practice. Full-time academic.</p> <p>3 Q. So at no time between 2001, when you came to</p> <p>4 West Virginia, to 2010 were you ever in private</p> <p>5 practice?</p> <p>6 A. Not at all.</p> <p>7 Q. And to carry that forward, between 2010 to</p> <p>8 today, at no time have you been in private</p> <p>9 practice, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. You would consider yourself an academic</p> <p>12 practice from 2001 to the present?</p> <p>13 A. Yes.</p> <p>14 Q. And as an academic, are you paid by -- and</p> <p>15 forgive me for not knowing, but are you essentially</p> <p>16 paid by the taxpayers?</p> <p>17 A. Our salary comes partially from the state,</p> <p>18 and our salary also comes from the university.</p> <p>19 Q. Which is the university is funded in part by</p> <p>20 the state, correct?</p> <p>21 A. Well, the university part is more the</p> <p>22 medical school part, which is the practice plan.</p> <p>23 So there's a portion of our salary is state</p> <p>24 funding and a portion of our salary is practice</p>	<p style="text-align: right;">Page 24</p> <p>1 course several evenings a week, just to kind of wet</p> <p>2 your whistle and get your feet wet with this. And</p> <p>3 then the 2005 was an online program with some weeks</p> <p>4 on campus to achieve the MBA over a one-year</p> <p>5 period.</p> <p>6 Q. And would you agree with me that that</p> <p>7 relates to the business of healthcare?</p> <p>8 A. It relates partially to the business of</p> <p>9 healthcare. It also relates to the understanding</p> <p>10 of how to improve workflow and how to make a better</p> <p>11 healthcare system. It's not all about money, you</p> <p>12 know. Certainly money, you think MBA, you think</p> <p>13 money, but it's also about improving your processes</p> <p>14 and improving patient experiences and physician</p> <p>15 experiences through a system.</p> <p>16 Q. Well, in discussing money for a second, why</p> <p>17 don't we move on.</p> <p>18 As someone in academics, you're well aware</p> <p>19 of the issue of bias, right?</p> <p>20 A. Um-hmm.</p> <p>21 Q. What does that mean to you?</p> <p>22 A. Bias is a curbed opinion or a swayed opinion</p> <p>23 based on some circumstance.</p> <p>24 Q. And I don't want to retread old ground</p>
<p style="text-align: right;">Page 23</p> <p>1 funding.</p> <p>2 Q. But whether or not you treat patients,</p> <p>3 you're still not engaged in what you would call</p> <p>4 private practice, right?</p> <p>5 A. Not at all.</p> <p>6 Q. Thank you. You've listed that you're a</p> <p>7 certified Six Sigma Black Belt?</p> <p>8 A. Um-hmm.</p> <p>9 Q. What is that?</p> <p>10 A. Six Sigma is a methodology of improving</p> <p>11 process and flow through a variety of business</p> <p>12 systems. I took that as an online course in</p> <p>13 conjunction with completing my MBA in 2005, just to</p> <p>14 have knowledge of that system to help better</p> <p>15 further our healthcare system, our WVU healthcare</p> <p>16 system to be more economical, to be more oriented,</p> <p>17 so that we can undertake tasks in a logical manner,</p> <p>18 reduce waste, improve productivity across the</p> <p>19 institution.</p> <p>20 Q. And just so we're clear, you mentioned an</p> <p>21 MBA program. You took courses both at -- in West</p> <p>22 Virginia and at the University of Tennessee of</p> <p>23 Knoxville with respect to an MBA, right?</p> <p>24 A. Yeah. The WVU program was just a one-month</p>	<p style="text-align: right;">Page 25</p> <p>1 that you've already testified about, but it's my</p> <p>2 understanding that you agree that it's not a good</p> <p>3 idea to induce physicians to buy a product on</p> <p>4 anything other than science and good medicine,</p> <p>5 right?</p> <p>6 MS. ROBINSON: Object to form.</p> <p>7 A. Say that again.</p> <p>8 Q. Well, let me preface where I'm going. I</p> <p>9 don't want to retread your prior testimony, for</p> <p>10 example, that you gave in the Edwards case. But I</p> <p>11 just want to explore this issue of bias with you a</p> <p>12 little bit more, so that's why I'm asking this</p> <p>13 question. So what I'm saying is -- let me start</p> <p>14 over.</p> <p>15 You agree with me it's not a good idea to</p> <p>16 induce physicians to buy products from a medical</p> <p>17 device manufacturer based on anything but science</p> <p>18 and good medicine, right?</p> <p>19 A. I don't know what you mean by "induce."</p> <p>20 What does that mean?</p> <p>21 Q. Well, you used the word "induce" in the</p> <p>22 Edwards deposition, so what do you think it means?</p> <p>23 A. I don't remember the details of that. If</p> <p>24 you'd like to show me that, I can read you what I</p>

<p style="text-align: right;">Page 26</p> <p>1 had written.</p> <p>2 Q. I don't want you to read me what you wrote.</p> <p>3 I want you to tell me what you think "induce"</p> <p>4 means as it relates to physicians and healthcare</p> <p>5 and bias.</p> <p>6 Can you do that?</p> <p>7 A. I'm not sure where you're going with this,</p> <p>8 and I don't know --</p> <p>9 Q. And I'm not trying to be flippant at all.</p> <p>10 It doesn't matter where I'm going at this point.</p> <p>11 What I'm asking you for is your understanding of</p> <p>12 the word "induce."</p> <p>13 It's your understanding. It's not mine.</p> <p>14 And you've used the word before, in all fairness.</p> <p>15 A. Okay.</p> <p>16 Q. So just exploring generally this idea of</p> <p>17 bias, which I think you've had some things to say</p> <p>18 about and agree with me that it's not a good idea</p> <p>19 to, for example, take a physician on an exotic trip</p> <p>20 simply to get them to buy a product, right?</p> <p>21 MS. ROBINSON: Object to form.</p> <p>22 A. Well, now, I understand what you're saying</p> <p>23 with the word "induce." You know, induce could be</p> <p>24 to hint or to suggest or to gently nudge and say,</p>	<p style="text-align: right;">Page 28</p> <p>1 respect to the study, right?</p> <p>2 MS. ROBINSON: Object to the form.</p> <p>3 A. Well, paid by who and for what?</p> <p>4 Q. You don't understand what I'm asking?</p> <p>5 A. No. No. I don't understand what you're</p> <p>6 trying to say. Try again.</p> <p>7 Q. Because we're being polite to each other, I</p> <p>8 will try again.</p> <p>9 Do you believe it is appropriate for a</p> <p>10 medical device manufacturer to pay, for example, a</p> <p>11 doctor who is running a clinical trial based upon</p> <p>12 the outcome of that clinical trial?</p> <p>13 MS. ROBINSON: Object to form.</p> <p>14 A. Not based on the outcome. Based on the</p> <p>15 materials that are needed to conduct the study, if</p> <p>16 it were a product and they provide a product for</p> <p>17 it. If it were cost-related to undertaking the</p> <p>18 study and coordinators or research or imaging</p> <p>19 studies or things like that, yes. But based on an</p> <p>20 outcome, a defined outcome that you have to achieve</p> <p>21 a certain thing beforehand, that's a different</p> <p>22 story.</p> <p>23 Q. What do you mean by "that's a different</p> <p>24 story"?</p>
<p style="text-align: right;">Page 27</p> <p>1 "We'd like you to do something." So when you use</p> <p>2 the word "induce" in terms of trips or large</p> <p>3 monetary things, then, no, it shouldn't be done.</p> <p>4 Now, if induce means that we'd like to pay</p> <p>5 for your expenses to go to a meeting to learn</p> <p>6 something, I think that's a reasonable thing.</p> <p>7 Q. In fact, you've heard about trips where</p> <p>8 physicians have been taken in an attempt to get</p> <p>9 them to induce -- to get them to buy a certain</p> <p>10 product from a company, right?</p> <p>11 A. I've heard about that, yes.</p> <p>12 Q. And you don't agree with that?</p> <p>13 A. I don't think that that should exist in</p> <p>14 healthcare.</p> <p>15 Q. And you would agree with me that a company,</p> <p>16 for example, a medical device manufacturer,</p> <p>17 shouldn't pay for a study based upon the outcome of</p> <p>18 that study?</p> <p>19 A. I don't know the specifics of what you mean</p> <p>20 by that. What do you mean by that?</p> <p>21 Q. Well, let me give you an example.</p> <p>22 If you're running a study at your center,</p> <p>23 you shouldn't be paid based upon the outcome. The</p> <p>24 outcome should be whatever it's going to be with</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Well, I don't think it's appropriate for</p> <p>2 someone to be paid for something and require</p> <p>3 them to achieve a certain outcome. In other</p> <p>4 words, "You have to have a 100 percent success rate</p> <p>5 of some procedure, or we're not going to fund your</p> <p>6 procedure." I don't think that that's appropriate.</p> <p>7 Q. Well, what if you're paid a bonus if you get</p> <p>8 a 100 percent success rate?</p> <p>9 A. You could be paid a bonus.</p> <p>10 Q. Do you think that's appropriate?</p> <p>11 A. It could be, based on outcomes that were</p> <p>12 discussed, mutually discussed before a trial began,</p> <p>13 if people had done that. And that's just the</p> <p>14 industry paying for something. That's not</p> <p>15 published in a journal in that way.</p> <p>16 Yeah, I mean, now, if something like that is</p> <p>17 published and that support is not mentioned, that's</p> <p>18 inappropriate. But certainly, they can be funded</p> <p>19 based on the agreement between two people.</p> <p>20 Q. So you think if somebody was paid a bonus if</p> <p>21 they had, for example, no complications, they</p> <p>22 received a substantial bonus, you think the fact</p> <p>23 that there is a bonus and the amount of that bonus</p> <p>24 should be disclosed in the study once it's</p>

<p style="text-align: right;">Page 30</p> <p>1 published?</p> <p>2 MS. ROBINSON: Object to form. I</p> <p>3 don't know if that correctly states his</p> <p>4 testimony.</p> <p>5 A. Yeah, I don't know. These are things that</p> <p>6 have to be discussed between industry and the</p> <p>7 individuals undertaking the study. They can</p> <p>8 discuss, "This is the sum of money that we're</p> <p>9 giving you, and these are the outcomes that we're</p> <p>10 looking for, and if these are achieved, these may</p> <p>11 be compensated in some way." I can't put a</p> <p>12 monetary value. I would not do that, and I</p> <p>13 wouldn't engage in that, personally.</p> <p>14 Q. Why not?</p> <p>15 A. Because I want to be involved in randomized</p> <p>16 trials. I want to be the one doing the</p> <p>17 randomizing. If I'm sponsored, I just want to be</p> <p>18 sponsored for expenses or things that are related</p> <p>19 to that. That's just my bias. That's my opinion.</p> <p>20 Q. Okay. So let's go back and answer my</p> <p>21 question, though. What I was trying to get at was</p> <p>22 whether or not you thought -- whether or not I was</p> <p>23 correct in understanding you, that if you are paid</p> <p>24 a bonus based for a 100 percent success rate in a</p>	<p style="text-align: right;">Page 32</p> <p>1 percent success rate with respect to that clinical</p> <p>2 trial and the results of that trial are published,</p> <p>3 that there needs to be full disclosure with respect</p> <p>4 to the bonus in that amount, right?</p> <p>5 MS. ROBINSON: Object to form. Asked</p> <p>6 and answered.</p> <p>7 A. I told you that their involvement needs to</p> <p>8 be disclosed.</p> <p>9 Q. When you said "their involvement," you mean</p> <p>10 the bonus?</p> <p>11 A. The financial support. I'm not saying that</p> <p>12 they have to list the amount of what it is. I</p> <p>13 think they need to list that significant funding</p> <p>14 was provided from this company for this research,</p> <p>15 or so and so has this agreement -- this</p> <p>16 investigator has this agreement with this industry.</p> <p>17 Q. In other words -- let's go to this case.</p> <p>18 Ethicon, if they're paying for a study, that needs</p> <p>19 to be disclosed?</p> <p>20 MS. ROBINSON: Object to form.</p> <p>21 A. I don't know. If they're paying for the</p> <p>22 study in what way? So they're sponsoring the --</p> <p>23 a study in question? It should be disclosed if</p> <p>24 they're sponsoring a study.</p>
<p style="text-align: right;">Page 31</p> <p>1 clinical trial that is later published, that the</p> <p>2 amount of that bonus and the fact that there is a</p> <p>3 bonus should be disclosed in the publication?</p> <p>4 A. Actually, now, with disclosure statements</p> <p>5 for our own societies, those numbers are disclosed,</p> <p>6 if somebody's receiving research money and how much</p> <p>7 that is and for exactly what that is.</p> <p>8 Q. I'm not talking about now. I'm talking</p> <p>9 about your opinion as it exists. What do you think</p> <p>10 about it?</p> <p>11 A. I think that now, that that's how things</p> <p>12 should be.</p> <p>13 Q. Do you think that it's appropriate to do</p> <p>14 that five years ago?</p> <p>15 A. I think that's appropriate to do that</p> <p>16 five years ago.</p> <p>17 Q. Why?</p> <p>18 A. Because when you interpret information, you</p> <p>19 want to know, was it sponsored, and if so, what</p> <p>20 level of sponsorship was it and what was the</p> <p>21 involvement of the participants.</p> <p>22 Q. And all I'm trying to get at is that you and</p> <p>23 I agree that if a physician who is conducting a</p> <p>24 clinical trial is paid a bonus based upon a 100</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. You've given testimony about ghostwriting</p> <p>2 before, right?</p> <p>3 A. Yes.</p> <p>4 Q. And what do you think of it?</p> <p>5 A. I think that writers can help others write</p> <p>6 manuscripts or papers, and certainly that happens.</p> <p>7 Q. Writers can help others. What do you mean?</p> <p>8 Be more specific, please.</p> <p>9 A. In other words, you have a paper that's</p> <p>10 written. It may be written by someone else at</p> <p>11 another level. It may be from industry. It may</p> <p>12 be -- may be someone who's your lab instructor who</p> <p>13 you work with, or your lab, you know, faculty</p> <p>14 member, and they're writing a paper and you're part</p> <p>15 of it and you'll offer your contributions and</p> <p>16 opinions to it. But you need to have -- take</p> <p>17 ownership for that material if you're part of it.</p> <p>18 Q. What do you mean by taking ownership?</p> <p>19 A. Well, if your name is on it, that means that</p> <p>20 you would agree with what's being said.</p> <p>21 Q. If a company representative has made</p> <p>22 editorial changes to an article, should that be</p> <p>23 disclosed in the final publication of the article?</p> <p>24 A. How do we know -- I don't know who they were</p>

<p style="text-align: right;">Page 34</p> <p>1 and how they did that or why they did that.</p> <p>2 Q. My question's much more simple. I'm not</p> <p>3 asking why they did it or those sorts of things.</p> <p>4 I'm just asking you a much more basic question.</p> <p>5 Can you answer it?</p> <p>6 A. They probably -- it would depend on the</p> <p>7 specifics of what they edited. You know, did they</p> <p>8 edit and say that no one had any erosions in a</p> <p>9 case when they actually had ten erosions? Then</p> <p>10 that's faulty. Depends on what they edited. Is it</p> <p>11 a minor edit? Is it a complete misrepresentation</p> <p>12 of something?</p> <p>13 Q. So, in other words, if they provide</p> <p>14 information or alter information, that probably</p> <p>15 should be disclosed?</p> <p>16 MS. ROBINSON: Object to form.</p> <p>17 A. If they alter information that would have a</p> <p>18 significant impact on someone's interpretation,</p> <p>19 that would be important to know.</p> <p>20 Q. Let's move on. You were a Bard Uretex</p> <p>21 user, correct?</p> <p>22 A. Um-hmm.</p> <p>23 Q. Is Uretex spelled U-R-E-T-E-X?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 36</p> <p>1 bit differently before. So let me state what I</p> <p>2 understand, and you tell me whether I'm right or</p> <p>3 wrong.</p> <p>4 I'll make it simple. Before 2004, you were</p> <p>5 primarily a Bard Uretex user when you were the</p> <p>6 surgeon performing the stress urinary incontinence</p> <p>7 surgery, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. And TVT was used, for example, at some</p> <p>10 points when you were a resident?</p> <p>11 A. Sometimes when I was a resident and also</p> <p>12 working with a -- gynecology colleagues who we'd</p> <p>13 worked with as well.</p> <p>14 Q. And that was my next question, so let me ask</p> <p>15 that in the next sentence.</p> <p>16 What changed in 2004 that caused you to</p> <p>17 start using Ethicon products?</p> <p>18 A. Well, the Prolift mesh had come out as well.</p> <p>19 The obturator approach had certainly changed the</p> <p>20 traditional way of doing TVTs to an easier, more</p> <p>21 simplistic way of approaching things, and if we can</p> <p>22 avoid potential for bladder injury, I think that</p> <p>23 would be good because with the Uretex, it was a</p> <p>24 little higher incidence of that.</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. And what did you use that product for?</p> <p>2 A. I used that for suburethral slings.</p> <p>3 Q. To treat stress urinary incontinence in</p> <p>4 women?</p> <p>5 A. Yes.</p> <p>6 Q. And when I use the acronym SUI, you know I'm</p> <p>7 referring to stress urinary incontinence, correct?</p> <p>8 A. Um-hmm.</p> <p>9 Q. And it's fair to say that before 2004 you</p> <p>10 were a Bard Uretex user and not a TVT user, right?</p> <p>11 A. I used them both.</p> <p>12 Q. Are you sure about that?</p> <p>13 A. Yep.</p> <p>14 Q. Have you ever testified differently?</p> <p>15 A. I've -- I used a lot more Bard than I had</p> <p>16 used TVT for a short period of time, but I used TVT</p> <p>17 as a resident and in some of the other cases that</p> <p>18 were done in working with our gynecology faculty,</p> <p>19 if they were going to use that or the resident</p> <p>20 wanted to use that, we would use that. But I did</p> <p>21 use Bard for quite a bit of time from 2001 to 2004</p> <p>22 or so.</p> <p>23 Q. And I'm not suggesting anything, but it</p> <p>24 sounds like you may have explained things a little</p>	<p style="text-align: right;">Page 37</p> <p>1 Also, I thought the quality of the mesh</p> <p>2 would be better and easier to implant. I like the</p> <p>3 concept of trocar-based that's similar to Prolift</p> <p>4 in that the material -- the materials were easy to</p> <p>5 use, easy to work with.</p> <p>6 Q. What was it about the quality of a TVT mesh</p> <p>7 versus a Bard Uretex mesh that caused you to change</p> <p>8 your --</p> <p>9 A. I thought it was softer. I thought upon</p> <p>10 implantation I liked how the mesh would sit in its</p> <p>11 appropriate place, and it was very easy to do. It</p> <p>12 was very easy and quick. It avoided the risk of</p> <p>13 bladder injury, especially when the obturator</p> <p>14 approach changed a lot of the things that we do.</p> <p>15 Using the obturator fossa really has cut down on</p> <p>16 risk of bladder injuries, risk of postoperative</p> <p>17 pain, risk of voiding dysfunction.</p> <p>18 Q. In fact, you'd agree with me that the TVT-O</p> <p>19 was invented to avoid some of those risks that</p> <p>20 the TVT presented, which included bladder injuries?</p> <p>21 A. It certainly would improve those risks, yes.</p> <p>22 Q. Do you have partners in your academic</p> <p>23 practice?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. How many?</p> <p>2 A. We have, myself now included, five.</p> <p>3 Q. And what does having a partner mean to you?</p> <p>4 A. It means you work together.</p> <p>5 Q. You share information?</p> <p>6 A. About patient care.</p> <p>7 Q. Do you share information about</p> <p>8 complications?</p> <p>9 A. We do.</p> <p>10 Q. And do you share information that may come</p> <p>11 up in literature?</p> <p>12 A. Yeah. Well, part of, you know, journal</p> <p>13 clubs and conferences, yes.</p> <p>14 Q. In other words, you share healthcare</p> <p>15 information with each other and expect your</p> <p>16 partners to candidly share information with you</p> <p>17 when they discuss it?</p> <p>18 A. Um-hmm.</p> <p>19 Q. How many years of experience do you have</p> <p>20 with these partners?</p> <p>21 A. With our longest one, 15.</p> <p>22 Q. You believe Ethicon's a partner of yours,</p> <p>23 right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 40</p> <p>1 A. I have not, no.</p> <p>2 Q. Now, with respect to any of these surgeries</p> <p>3 that you performed, including those with</p> <p>4 polypropylene mesh, it's important for you to have</p> <p>5 scientific data before you implant that product,</p> <p>6 right?</p> <p>7 A. Yes.</p> <p>8 MS. ROBINSON: Object to form.</p> <p>9 A. Yes.</p> <p>10 Q. Or perform the procedure, if it's only</p> <p>11 procedure-based?</p> <p>12 A. We'll perform it, yes.</p> <p>13 Q. And you wouldn't just implant a device or do</p> <p>14 a procedure on a woman without having that data,</p> <p>15 correct?</p> <p>16 MS. ROBINSON: Object to form.</p> <p>17 A. The data is important, but understanding the</p> <p>18 procedure that you're going to do and how does it</p> <p>19 relate to things that you've done already,</p> <p>20 experience from lectures and national meetings on</p> <p>21 this, is certainly important, as well, so it's a</p> <p>22 combination of things.</p> <p>23 Q. And those -- the combination of those</p> <p>24 things, including the data supporting the safety</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. And you expect the same from Ethicon, that</p> <p>2 if it has information about its products that may</p> <p>3 impact on your delivery of healthcare, you want to</p> <p>4 know that information?</p> <p>5 A. Right.</p> <p>6 Q. What other surgeries have you done to treat</p> <p>7 stress urinary incontinence?</p> <p>8 A. I've done pubovaginal slings. I've done Raz</p> <p>9 needle suspensions, Pereyra and Stamey needle</p> <p>10 suspensions. We've done certainly slings. We've</p> <p>11 done injections of material into the bladder neck.</p> <p>12 I've assisted with MMKs and Burches when we do open</p> <p>13 things with the gynecologists, only if they've</p> <p>14 asked me to help them for some pelvic reason. But</p> <p>15 really, just you're helping them and it's their</p> <p>16 procedure.</p> <p>17 Q. Do you ever have a complication with a</p> <p>18 patient under general anesthesia?</p> <p>19 A. Such as -- you can have any complication,</p> <p>20 sure.</p> <p>21 Q. I guess I'm asking a more specific question.</p> <p>22 Have you ever had a complication during</p> <p>23 surgery with a patient that had to do with the</p> <p>24 anesthesia being delivered?</p>	<p style="text-align: right;">Page 41</p> <p>1 and efficacy of the procedure, would apply to</p> <p>2 either a procedure or an implant, right?</p> <p>3 A. Combination of things, yes.</p> <p>4 Q. And with respect to the use of Ethicon mesh,</p> <p>5 you would want to know that your healthcare</p> <p>6 partner, Ethicon, gave you the necessary</p> <p>7 information to make the right decision when</p> <p>8 deciding to use the TVT, right?</p> <p>9 MS. ROBINSON: Object to form.</p> <p>10 A. I would want to know the pertinent</p> <p>11 information that relates to me, yes.</p> <p>12 Q. And what type of information did you look at</p> <p>13 to satisfy yourself that the TVT was safe and</p> <p>14 effective when you started using it in your own</p> <p>15 surgeries in or about 2004?</p> <p>16 A. I'd look at the instructions. I'd look at</p> <p>17 the presentations that were done at the AUA about</p> <p>18 that time, what abstracts were presented,</p> <p>19 information from other colleagues on an academic</p> <p>20 level, you know, if we had a regional meeting and</p> <p>21 these things were discussed, certainly, these</p> <p>22 things would come into play.</p> <p>23 Q. What else?</p> <p>24 A. And your personal bias. I think switching</p>

<p style="text-align: right;">Page 42</p> <p>1 from Bard to switching from GYNECARE is actually</p> <p>2 very easy. It's an easier product to do. It</p> <p>3 follows the same things I've been doing. At that</p> <p>4 point in 2004, I've been doing this for eight</p> <p>5 years already, including my residency. So here,</p> <p>6 all of a sudden, there's a better product, it's</p> <p>7 easier to use, and it's very straightforward.</p> <p>8 Q. Did you rely on information from Ethicon</p> <p>9 besides the instructions for use?</p> <p>10 A. No.</p> <p>11 Q. Why not?</p> <p>12 A. Didn't need to.</p> <p>13 Q. Why not?</p> <p>14 A. Because it's just a variation of what I've</p> <p>15 been doing for eight years. You know, whatever</p> <p>16 complication was going to happen, I would've seen</p> <p>17 it over the eight years or heard about it or had</p> <p>18 those patients sent up to me.</p> <p>19 One of the things about being a referral</p> <p>20 center, where we are, is the -- a lot of</p> <p>21 challenging patients that others have operated on,</p> <p>22 so many of the issues that I would expect to see,</p> <p>23 I had seen already.</p> <p>24 Q. So you thought you already knew what you</p>	<p style="text-align: right;">Page 44</p> <p>1 how to do things. That shaped the knowledge that</p> <p>2 we have.</p> <p>3 Q. Take a step back for a moment, though.</p> <p>4 You know that there are thousands of women</p> <p>5 that have claimed injuries from the implant of</p> <p>6 vaginal mesh, right?</p> <p>7 MS. ROBINSON: Object to form.</p> <p>8 A. Many people have claimed that, yes.</p> <p>9 Q. Would you, as you sit here today, agree with</p> <p>10 me that perhaps that mesh was too widely distribu-</p> <p>11 ted to physicians and hospitals and put in too many</p> <p>12 women too fast by experienced -- or I'm sorry, by</p> <p>13 physicians who were not as experienced as you?</p> <p>14 MS. ROBINSON: Object to form.</p> <p>15 A. No.</p> <p>16 Q. Why not?</p> <p>17 A. I think that these physicians who implant,</p> <p>18 or whatever surgery they did, need to have a full</p> <p>19 understanding based on their skills and their</p> <p>20 training about what they're going to do, and they</p> <p>21 should be able to look at a product -- I mean,</p> <p>22 mesh is no different than Prolene sutures we've</p> <p>23 closed abdomens with and the same Prolene sutures</p> <p>24 we've done MMKs with or Burches. So they should</p>
<p style="text-align: right;">Page 43</p> <p>1 were doing and you understood the material and the</p> <p>2 procedure enough to go forward?</p> <p>3 A. Um-hmm.</p> <p>4 Q. Did you look to peer review journals for</p> <p>5 data on the safety and efficacy of the TVT device?</p> <p>6 A. Yes.</p> <p>7 Q. What journals?</p> <p>8 A. "Journal of Urology," the "Gold Journal,"</p> <p>9 many of the urogynecology journals, abstracts</p> <p>10 presented at the AUA, updates to Campbell's</p> <p>11 "Urology," "Female Urology," Shlomo Raz's initial</p> <p>12 texts to learn about these procedures. A variety</p> <p>13 of different sources.</p> <p>14 Q. In other words, you felt after looking at</p> <p>15 this data and having the experience of implanting</p> <p>16 mesh for eight years that the use of mesh and</p> <p>17 specifically Ethicon mesh in your hands was safe?</p> <p>18 A. Yes.</p> <p>19 Q. And you thought that, in part at least,</p> <p>20 based upon your own understanding and confidence</p> <p>21 and your skill level?</p> <p>22 A. Yes. But also, you know, each year another</p> <p>23 paper would come out. More information would come</p> <p>24 out, case reports, other experiences, variations of</p>	<p style="text-align: right;">Page 45</p> <p>1 know that based on their skills and training that</p> <p>2 this is just a different application of something</p> <p>3 that they've been doing for years. And their</p> <p>4 knowledge, their skills, that should be what moves</p> <p>5 forward to whether they're going to adopt something</p> <p>6 or not adopt something.</p> <p>7 Q. That's not an answer to my question, though.</p> <p>8 My question was whether or not you believe that</p> <p>9 mesh -- let me back up for a second.</p> <p>10 I think you and I agree, don't we, that</p> <p>11 physicians should be skilled in a procedure before</p> <p>12 they do that procedure, correct?</p> <p>13 A. Physicians should be skilled in a procedure,</p> <p>14 yes.</p> <p>15 Q. So we agree on that. What I'm asking you,</p> <p>16 though, is something different, which is, do you</p> <p>17 believe that mesh was too widely distributed and</p> <p>18 put in too many women too fast by inexperienced</p> <p>19 physicians, which is perhaps one of the reasons why</p> <p>20 we're seeing all these claims?</p> <p>21 MS. ROBINSON: Object to form.</p> <p>22 A. I don't think it had to do with the</p> <p>23 physicians' experience. I think that the</p> <p>24 physicians who were using mesh are very</p>

<p style="text-align: right;">Page 46</p> <p>1 experienced. I don't think that they selected</p> <p>2 their patients carefully based on their skills and</p> <p>3 training. I think mesh is -- has done some amazing</p> <p>4 things for people. You're only talking about all</p> <p>5 the negative things. I don't have anything</p> <p>6 negative to say about it. Mesh has shaped the way</p> <p>7 we do surgery. Mesh has changed outcomes for</p> <p>8 people that never would have the outcomes that</p> <p>9 they do in a positive way.</p> <p>10 Q. You mentioned that they made a mistake in</p> <p>11 the selection of their patients.</p> <p>12 What do you mean by that?</p> <p>13 A. The IFU is very clear. It's very clear.</p> <p>14 The first iteration of the IFU is very obvious.</p> <p>15 Mesh is used in the treatment of stress urinary</p> <p>16 incontinence. It's a treatment for stress urinary</p> <p>17 incontinence. It's not a prevention. It's not</p> <p>18 going to -- it's not going to treat something</p> <p>19 that's not there. It doesn't say it's a treatment</p> <p>20 for urge incontinence or mixed incontinence. It's</p> <p>21 a treatment for stress incontinence.</p> <p>22 It's very clear. Many people who have</p> <p>23 implanted slings have not considered its true</p> <p>24 indication. And when you implant mesh in those</p>	<p style="text-align: right;">Page 48</p> <p>1 some other type of incontinence?</p> <p>2 A. That's correct.</p> <p>3 Q. And you believe that in seeing these</p> <p>4 complications, that that behavior by these</p> <p>5 physicians may be, in fact, a cause of those</p> <p>6 complications, right?</p> <p>7 A. That's correct.</p> <p>8 Q. And I said to you, why do you believe those</p> <p>9 complications come about?</p> <p>10 A. You have to look at the revisions of mesh,</p> <p>11 the mesh removals to determine that. And when you</p> <p>12 look at, in our practice, in which we've removed</p> <p>13 probably close to 200 patients' mesh since we</p> <p>14 started counting them, paying attention to that,</p> <p>15 very few patients have had erosions. Most</p> <p>16 patients, when you look at the original indication,</p> <p>17 they had mixed incontinence, or they had urge</p> <p>18 incontinence, or the sling was placed prophylac-</p> <p>19 tically. And when you do that -- and that's</p> <p>20 well documented. When you do these procedures, or</p> <p>21 any stress incontinence procedure for that matter,</p> <p>22 it's more likely to fail. And then, of course,</p> <p>23 there's the patient comorbidities. Okay.</p> <p>24 Q. Let's stop there before we go on to</p>
<p style="text-align: right;">Page 47</p> <p>1 people, they have -- they are more likely than less</p> <p>2 likely to have problems.</p> <p>3 Q. Why?</p> <p>4 MS. ROBINSON: Can we go off the record</p> <p>5 for a second?</p> <p>6 MR. WALLACE: Yeah. Go ahead.</p> <p>7 (Brief break.)</p> <p>8 BY MR. WALLACE:</p> <p>9 Q. Just answer the why, and then we'll take a</p> <p>10 break.</p> <p>11 A. Just reorient me to the -- you know.</p> <p>12 Q. My understanding of your testimony is that</p> <p>13 you believe, as a physician who's implanted mesh</p> <p>14 for a number of years, that one of the reasons why</p> <p>15 there are so many complications with mesh is</p> <p>16 because of patient selection, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And that you believe, in part, that</p> <p>19 physicians, when they're doing patient selection,</p> <p>20 have sometimes implanted mesh in women that didn't</p> <p>21 need it?</p> <p>22 A. That's correct.</p> <p>23 Q. And including in women that may not be</p> <p>24 suffering from stress urinary incontinence but</p>	<p style="text-align: right;">Page 49</p> <p>1 comorbidities.</p> <p>2 You said it's well documented. What do you</p> <p>3 mean by that?</p> <p>4 A. Well, the literature has described for years</p> <p>5 about who is more or less likely to do well when</p> <p>6 they have a sling placed. And it's well documented</p> <p>7 that patients with urge incontinence -- pure urge</p> <p>8 incontinence, that is -- patients with mixed</p> <p>9 incontinence, patients with multiple comorbidities,</p> <p>10 patients who were having multiple procedures done</p> <p>11 at the same time, like a hysterectomy and anterior</p> <p>12 repair and a sling, are more likely to do poorly as</p> <p>13 opposed to someone who just has a mesh placed or a</p> <p>14 sling placed for stress incontinence.</p> <p>15 Q. Are there any peer review journals or</p> <p>16 articles that come to mind when you make that</p> <p>17 standpoint?</p> <p>18 A. About which statement?</p> <p>19 Q. The statement you just made about that</p> <p>20 literature or that it's well documented.</p> <p>21 A. Yes.</p> <p>22 Q. Which ones?</p> <p>23 A. The Schimpf, the variety of Cochrane</p> <p>24 reviews, the reviews from the "Journal of Urology"</p>

<p style="text-align: right;">Page 50</p> <p>1 as well. There are a variety of different reviews. 2 Q. Okay. Let's take a break. 3 (Brief break at 12:29 p.m.) 4 (Back on the record at 12:37 p.m.) 5 BY MR. WALLACE: 6 Q. You mentioned some of the other non-mesh 7 procedures that you've done where you use sutures. 8 Do you recall talking about that earlier 9 today? 10 A. Yes. 11 Q. Are -- is using a mesh and doing, for 12 example, a Burch procedure present the same risk? 13 A. Some are the same risk, but others are 14 different. 15 Q. What are the differences? 16 A. Well, mesh is placed under the urethra, 17 whereas Burch suspends it from above. So the 18 complaints could be different. Burch patients may 19 complain more of voiding dysfunction, difficulty 20 with their stream, urgency, frequency, obstructive 21 kind of symptoms. Yes, you can see that with TVT 22 mesh-based pubovaginal slings, as well, but it's 23 more urethral-related, more towards where the 24 urethral meatus is.</p>	<p style="text-align: right;">Page 52</p> <p>1 at the table, did you control for all the 2 different products that were examined? 3 A. You can't control for all of them. There's 4 too many products. There's too many things. 5 Because it's a meta-analysis, so what do you want 6 to pull out? Which study you're going to pull out? 7 Q. Right. But you're relying on Schimpf, for 8 example, to give me your answer -- 9 A. Right. 10 Q. -- so I'm trying to figure out how specific 11 you are. If you're just giving me a general 12 opinion based upon a meta-analysis, that's fair. 13 I just need to know that. 14 A. No. Most of the studies that were within 15 Schimpf, when you're looking at a pubovaginal 16 sling, for an example, there's only one of the 17 studies that used mesh for its pubovaginal sling. 18 All the other ones used autologous or cadaveric 19 material. So that's a fair comparison. You don't 20 have to pull anything out for that information, 21 okay? And the other ones, you know, use Burch or 22 MMK or other type of procedures. They're all 23 pretty standard, how they're done, so there's 24 really not a lot of factoring.</p>
<p style="text-align: right;">Page 51</p> <p>1 You can have more dyspareunia with 2 vaginal-based procedures as opposed to Burch-based 3 procedures, but that -- often they're combined 4 with other procedures, so they may be having an 5 anterior repair and a hysterectomy and an 6 incontinence procedure, so you have to look at the 7 whole picture of what they're having done as 8 opposed to just the individual A versus B. 9 Q. But you would agree with me that there is a 10 risk of greater dyspareunia with a vaginal mesh 11 procedure? 12 A. Not necessarily. Again, it's the patient 13 factor. So you operate on someone who's 14 postmenopausal, you can have dyspareunia with 15 either procedure, just because they're 16 postmenopausal. 17 Q. But you can have greater dyspareunia with a 18 vaginally-placed mesh product? 19 A. Not necessarily. I think that actually the 20 risk can be pretty similar. 21 Q. And what science or data do you base that 22 on? 23 A. Schimpf. It's to say that all procedures -- 24 Q. Did you control, in Schimpf, when you looked</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. So in other words -- and let's suppose 2 you're wrong, that your reading of Schimpf is 3 wrong, that it isn't a straight comparison, in 4 fact. Let's talk about autologous slings, for 5 example. 6 Do you think, when you use the word 7 "autologous" slings, are you saying that it only 8 had to do with fascia? 9 MS. ROBINSON: Object to form. 10 A. Autologous, by definition, means self, so 11 that means you got the fascia from that person. 12 Q. So when you're using the word "autologous" 13 fascial slings in connection with the Schimpf 14 article, you are not, for example, referring to 15 Gore-Tex? 16 A. Right. One of the papers within Schimpf, of 17 the ones that look at pubovaginal slings, that 18 used -- I think it was Gore-Tex. I have to look 19 specifically. I don't remember off the top of my 20 head. But the other ones used either cadaveric or 21 autologous fascia. 22 Q. Do you believe that the risks of using a 23 suture that may erode present the same risks of a 24 mesh that may erode?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. They both can be very significant, yes.</p> <p>2 Q. Do they present the same risks?</p> <p>3 A. I think they present similar risks. It</p> <p>4 depends on where the sutures are placed. You can</p> <p>5 do an MMK or a Burch and you can put a stitch right</p> <p>6 through the middle of the urethra and have a stone</p> <p>7 form on it or right through the bladder. And we've</p> <p>8 removed cases of people who have had Burches or</p> <p>9 MMKs and had erosion and had stones forming on</p> <p>10 their suture. So yeah, sutures that are</p> <p>11 inappropriately placed can certainly do that. Mesh</p> <p>12 that's inappropriately placed or a pubovaginal</p> <p>13 sling that's inappropriately placed can all have</p> <p>14 significant effects.</p> <p>15 Q. You said that there are different risks with</p> <p>16 mesh. What are they?</p> <p>17 A. I don't know that they're different -- well,</p> <p>18 some of the things relate to how they're implanted.</p> <p>19 You wouldn't expect someone who had an MMK versus</p> <p>20 a patient who had an obturator sling to have FIE</p> <p>21 pain because of, just inherent to how a needle has</p> <p>22 passed. So they may have a different subset of</p> <p>23 side effects based on the approach or what's been</p> <p>24 performed for them. Both can have voiding</p>	<p style="text-align: right;">Page 56</p> <p>1 A. No.</p> <p>2 Q. You would agree with me that there is no</p> <p>3 center, nor was there ever any healthcare center,</p> <p>4 that specialized in the removal of sutures in the</p> <p>5 treatment of stress urinary incontinence, correct?</p> <p>6 MS. ROBINSON: Objection to the form.</p> <p>7 A. That has that written on their logo, you</p> <p>8 know, on their advertisement, on their billboard?</p> <p>9 I've never seen that, no.</p> <p>10 Q. Putting aside whether or not somebody has it</p> <p>11 on a billboard, you would agree with me that that's</p> <p>12 never existed?</p> <p>13 A. I've never seen it.</p> <p>14 Q. Now, when a woman comes to you for treatment</p> <p>15 of stress urinary incontinence, do you typically</p> <p>16 examine her?</p> <p>17 A. Yes.</p> <p>18 Q. Do you do urodynamics testing?</p> <p>19 A. Yes.</p> <p>20 Q. And if the patient, for example, wants to</p> <p>21 bring in her spouse, is that okay to do?</p> <p>22 A. During what, during urodynamics testing?</p> <p>23 Q. During your pelvic exam, for example?</p> <p>24 A. Oftentimes they're in the room behind the</p>
<p style="text-align: right;">Page 55</p> <p>1 symptoms. Both can have pain. Both can have</p> <p>2 dyspareunia, but they may be for different reasons,</p> <p>3 or they may be for the same reason. You know, they</p> <p>4 may be -- like I said, they have atrophic</p> <p>5 vaginitis. They're postmenopausal. They're not</p> <p>6 on any estrogen. Or they have other risk factors,</p> <p>7 you know, age, parity, smoking, things like</p> <p>8 that.</p> <p>9 Q. Are you aware of these mesh pain clinics</p> <p>10 that have come about in the last few years?</p> <p>11 A. A mesh pain clinic?</p> <p>12 Q. For example, there's a clinic in North</p> <p>13 Carolina that specializes in the removal of mesh</p> <p>14 now.</p> <p>15 Are you familiar with that?</p> <p>16 A. No. No.</p> <p>17 Q. Are you familiar with the work that's going</p> <p>18 on at UCLA?</p> <p>19 A. Which is what?</p> <p>20 Q. That there are clinics that specialize in</p> <p>21 the removal of mesh?</p> <p>22 A. No.</p> <p>23 Q. Are you aware of any of the work that's</p> <p>24 being done in Atlanta in that area?</p>	<p style="text-align: right;">Page 57</p> <p>1 curtain, of course, but they can be present.</p> <p>2 Q. You don't have a problem with that?</p> <p>3 A. No.</p> <p>4 Q. And you believe it might provide some</p> <p>5 comfort to the woman that's being examined, right?</p> <p>6 MS. ROBINSON: Object to form.</p> <p>7 A. That's up to her. I will ask each patient,</p> <p>8 after I do an examination of them or recommend a</p> <p>9 procedure for them, I will ask them, "Do I need to</p> <p>10 speak to your family?" And "Do you want me to</p> <p>11 speak to your family?" And if they want me to,</p> <p>12 then I will, and discuss what's going on.</p> <p>13 Q. And the patient has a right to refuse</p> <p>14 treatment at any time?</p> <p>15 A. Yes, they do.</p> <p>16 Q. What is informed consent?</p> <p>17 A. Informed consent is a process by which a</p> <p>18 physician will speak to a patient regarding a</p> <p>19 procedure or a test that they're going to have and</p> <p>20 discuss with them the risks, the benefits, things</p> <p>21 that may happen along the way, and have them sign a</p> <p>22 generic form to document that that discussion was</p> <p>23 had. That's only one part of informed consent.</p> <p>24 There's also things that are implied, that are</p>

<p style="text-align: right;">Page 58</p> <p>1 assumed, and that are discussed about with patients</p> <p>2 that are not written on a form consent.</p> <p>3 Q. If you had diagnosed a woman with SUI and</p> <p>4 have decided that surgical intervention is</p> <p>5 appropriate, what options do you give that woman?</p> <p>6 A. I explain to them all of the options from</p> <p>7 nonsurgical treatments to surgical treatments.</p> <p>8 Q. And what surgical options do you give her?</p> <p>9 A. That depends on what their situation is. If</p> <p>10 someone has sphincteric incontinence, they could be</p> <p>11 offered injectable treatment. If they have</p> <p>12 hypermobility, they can be offered a sling via</p> <p>13 autologous, via -- we're talking pubovaginal. They</p> <p>14 can be offered a pubovaginal sling via autologous</p> <p>15 or cadaveric fascia. They can be offered a</p> <p>16 suburethral sling via mesh, and then now, for the</p> <p>17 most part, I do them by the obturator approach.</p> <p>18 Or they can be offered observation.</p> <p>19 Q. So you offer all those options to someone</p> <p>20 that's been treated or diagnosed with stress</p> <p>21 urinary incontinence?</p> <p>22 A. Yes.</p> <p>23 Q. And you would agree with me that some of</p> <p>24 those surgical options, like Burch and non-mesh</p>	<p style="text-align: right;">Page 60</p> <p>1 MS. ROBINSON: Object to form.</p> <p>2 A. For any patient who I'm treating for stress</p> <p>3 incontinence, that they should come back on an</p> <p>4 annual basis, but in particular, people who've had</p> <p>5 surgery. If someone is treated with observation</p> <p>6 and they want to come back, that's fine. I give</p> <p>7 them an appointment. But for any patient that has</p> <p>8 any surgical procedure, I want to follow them</p> <p>9 annually.</p> <p>10 Q. Do you have a standard informed consent form</p> <p>11 that you ask patients to read?</p> <p>12 A. I have a standard informed consent form. We</p> <p>13 use the hospital informed consent form. But I read</p> <p>14 to them an additional statement or statements that</p> <p>15 becomes a part of their medical record, about</p> <p>16 slings, the position statement on slings, the</p> <p>17 complications, and the problems that can happen</p> <p>18 with them. And I do that for every procedure.</p> <p>19 Q. And how long have you been doing that?</p> <p>20 A. I've been doing that since 2010.</p> <p>21 Q. So you'd agree with me that prior to 2010,</p> <p>22 you weren't reading that additional statement?</p> <p>23 A. No. I was telling them all these things,</p> <p>24 but, unfortunately, we're in a world now where you</p>
<p style="text-align: right;">Page 59</p> <p>1 sling procedures, are perfectly appropriate, within</p> <p>2 the standard of care?</p> <p>3 A. They can be offered to the patient, sure.</p> <p>4 Q. When you tell a woman that she can receive a</p> <p>5 mesh polypropylene sling, what are you telling her?</p> <p>6 A. Explain to them the details of the</p> <p>7 procedure. Explain to them the risks of the</p> <p>8 procedure, certainly, obvious things like bleeding,</p> <p>9 injury to other structures along the way, including</p> <p>10 the bladder. I discuss with them the risks of</p> <p>11 erosion and extrusion. I discuss with them the</p> <p>12 risks of pain, and I discuss with them the</p> <p>13 importance of following up with me on an annual</p> <p>14 basis because they may develop problems not only</p> <p>15 initially, but years down the road.</p> <p>16 Q. And how long have you been telling that to</p> <p>17 your patients?</p> <p>18 A. Since I started here.</p> <p>19 Q. 2001?</p> <p>20 A. Yes.</p> <p>21 Q. So it's your testimony that since 2004 you</p> <p>22 have told your patients that were deciding whether</p> <p>23 or not to receive a mesh-based polypropylene sling</p> <p>24 those things you just described?</p>	<p style="text-align: right;">Page 61</p> <p>1 need to do more than that.</p> <p>2 Q. What -- as opposed to unfortunate, you</p> <p>3 accused me of only looking at the negative things</p> <p>4 earlier. Isn't it more positive to look at it in a</p> <p>5 way that you're giving better informed consent now</p> <p>6 based upon the circumstances?</p> <p>7 MS. ROBINSON: Objection.</p> <p>8 A. No. I think I'm giving them fine informed</p> <p>9 consent. When I have a patient come in to me who's</p> <p>10 referred from -- just referred for a consideration</p> <p>11 and says that "I need you to take out my mesh</p> <p>12 because it's been recalled," you know, there's a</p> <p>13 problem with interpretation of the world. And I</p> <p>14 have patients that come in and say, "Well, I don't</p> <p>15 want mesh because it's bad for you."</p> <p>16 We have a problem. So we need to document</p> <p>17 better because patients will turn around -- and,</p> <p>18 you know, they may be contacted, patients are</p> <p>19 cold-called now. My patients have been cold-called</p> <p>20 about a sling, and, you know, they want to know if</p> <p>21 everything's okay. I certainly didn't call them,</p> <p>22 nor would I call them, but someone called them.</p> <p>23 So, you know, now, unfortunately, we're in a</p> <p>24 society where I know this is a standard procedure</p>

<p style="text-align: right;">Page 62</p> <p>1 that's done wonderfully for my patients, but I need 2 to document everything that goes on because these 3 are now big issues. 4 Q. Do you -- in documenting, do you keep a list 5 of all your patients that you've seen and put mesh 6 in over the years? 7 A. Do I keep a separate list of them? I have 8 access to that, yes. I can look and see who's 9 followed up with me, our EMR list. 10 Q. How many -- what percentage of your patients 11 have failed to follow up with you? 12 A. I don't know. I haven't looked at that and 13 summed that out. 14 Q. Well, so, why don't you look at page 4 of 15 Exhibit 3. Is that the Hendrix report? 16 And I'm sorry, Doctor, let's make sure 17 we're looking at the right thing. 18 A. The Hendrix report. 19 Q. Okay. Thank you. 20 So is it fair to say that your testimony is 21 that you have not kept an actual log of patient 22 satisfaction over the last 16 years since you've 23 been in West Virginia treating women for stress 24 urinary incontinence?</p>	<p style="text-align: right;">Page 64</p> <p>1 unsatisfied. 2 Q. Where's your proof? 3 A. I have a very good track record of -- I'm 4 the only subspecialist who does female pelvic 5 medicine in the state of West Virginia. So if 6 they're not going to come and follow with me, 7 they're going to go to Cleveland or Pittsburgh or 8 to another major center. So I'm the only 9 sub-boarded specialist in my area. I expect people 10 to follow with me. I'm very direct about their 11 need to follow on an annual basis, and when they 12 don't follow, then, you know, I can't be held -- 13 you know, I can't expect, you know, them to come 14 when I tell them to and they don't. 15 But it's very strong. I have people that -- 16 from back 15 years ago that still follow up because 17 they know it's important to do and they know when 18 they have problems to do. 19 Q. And I'm pleased to hear that you impress 20 that upon them. My questions, though, are more 21 basic. 22 As much as you might ask somebody to follow 23 up with you, a woman, if she is unsatisfied with 24 you, may choose not to, right?</p>
<p style="text-align: right;">Page 63</p> <p>1 A. You asked a whole lot of things. First, it 2 was a patient log. Now, you asked about a patient 3 satisfaction log. I mean, those are two different 4 things. 5 Q. Well, answer the question that I just asked, 6 then. 7 A. I don't know. I don't know what you're 8 asking. 9 Q. Well, you say you don't keep a separate log 10 relating to your patients, right? 11 A. No. I didn't say that. I said I only keep 12 a separate log of patients who've had implants. I 13 know all the patients that we see because our EMR 14 can follow those patients. I can look at the 15 diagnosis code, I can look at a procedure code, and 16 I can acquire information like that. But I have 17 looked at our long-term results of patients -- I 18 have not published it -- and slings that I have 19 done 15 years ago of the patients who are still in 20 our practice. I can tell how they're doing. 21 Q. But you can't sit here today and tell me 22 how many of those patients that you've put slings 23 in over the last 16 years are unsatisfied? 24 A. I would say that very few of them are</p>	<p style="text-align: right;">Page 65</p> <p>1 A. They might, but they probably won't. 2 They'll -- initially, they come to you, so it's 3 your opportunity, on the one shot that they're 4 unsatisfied, to figure out why. So most people 5 will come back when they're unsatisfied. You'll 6 get another shot since you did their surgery. 7 Q. So you disagree with literature suggesting 8 that 50 percent of women who are unsatisfied don't 9 follow up with the implanting physician? 10 A. I think that's -- I know what paper you're 11 referring to. But there's others that show that 12 they do follow up with their implanting physician. 13 Q. And in your experience, just based upon your 14 review of your EMR system, you think that there's 15 excellent follow-up at your facility? 16 A. I do think so, yes. 17 Q. But you can't give me a number or percentage 18 today of the women that have failed to follow-up 19 with you, right? 20 A. I can't. 21 Q. So in other words, when you see on page 4 of 22 the general TVT report that you've had excellent 23 long-term patient satisfaction over 14 years, you 24 can't provide me with any statistical evidence of</p>

<p style="text-align: right;">Page 66</p> <p>1 that, as you sit here today?</p> <p>2 A. No.</p> <p>3 Q. And you, because we're at your deposition,</p> <p>4 and you have brought documents, you haven't</p> <p>5 provided anything to us today that would allow us</p> <p>6 to make those calculations to verify the truth of</p> <p>7 this statement that I just read from page 4, right?</p> <p>8 A. Right. The statement is a true statement.</p> <p>9 But to verify that statement, actually, would</p> <p>10 require a study. It would require an IRB for me to</p> <p>11 look at my patients and to see who's satisfied and</p> <p>12 not satisfied to report that to you.</p> <p>13 Q. Well, you would agree with me, though, that</p> <p>14 we can't let anyone just say it's so just because</p> <p>15 I'm a great physician and I say it's so, right?</p> <p>16 Otherwise, anybody could come in the room and say</p> <p>17 whatever the heck they want, right?</p> <p>18 A. Right.</p> <p>19 Q. So do you agree with me you can't just come</p> <p>20 in the room and say it's so just because I say it's</p> <p>21 so?</p> <p>22 MS. ROBINSON: Object to form.</p> <p>23 A. We have to assume that people are being</p> <p>24 truthful in what they say.</p>	<p style="text-align: right;">Page 68</p> <p>1 A. Within the last year.</p> <p>2 Q. And you would agree with me that the</p> <p>3 instructions for use are a primary way in which a</p> <p>4 company can describe the procedure and give you the</p> <p>5 contraindications and the warnings, right?</p> <p>6 MS. ROBINSON: Object to form.</p> <p>7 A. They can do that based upon information that</p> <p>8 they know, whether they think it's important to be</p> <p>9 included in there.</p> <p>10 Q. Right. So if there are certain risks that</p> <p>11 may come with the procedure, it should be in the</p> <p>12 instructions for use, right?</p> <p>13 A. If it's unique to that procedure, then it</p> <p>14 should be included in it.</p> <p>15 Q. You would agree with me that the implant of</p> <p>16 a TVT can cause retropubic bleeding?</p> <p>17 A. The implant of a traditional TVT?</p> <p>18 Q. Yes.</p> <p>19 A. Yes, it could.</p> <p>20 Q. And it could cause erosion?</p> <p>21 A. Yes, it could.</p> <p>22 Q. It can cause extrusion?</p> <p>23 A. Yes, it could.</p> <p>24 Q. Can cause fistula formation?</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. But I have the right to cross-examine you</p> <p>2 and test the veracity of your statements, right?</p> <p>3 A. Sure.</p> <p>4 Q. And if I can't do that -- or I'm sorry, I</p> <p>5 can't do that with this statement except just take</p> <p>6 your word for it?</p> <p>7 A. That's correct.</p> <p>8 Q. I have no independent data to look to or</p> <p>9 test?</p> <p>10 A. That's correct.</p> <p>11 Q. You said earlier you read the instructions</p> <p>12 for use?</p> <p>13 A. Um-hmm.</p> <p>14 Q. And do you read the instructions for use</p> <p>15 every time you do a surgery?</p> <p>16 A. Initially, sure.</p> <p>17 Q. When's the last time you put in a TVT?</p> <p>18 A. Last week.</p> <p>19 Q. Did you read the instructions for use before</p> <p>20 you did it?</p> <p>21 A. Not before that procedure. I've looked at</p> <p>22 it in the past.</p> <p>23 Q. When's the last time you looked at the TVT</p> <p>24 instructions for use?</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Mm-hmm.</p> <p>2 Q. Chronic inflammation?</p> <p>3 A. I don't know about chronic inflammation.</p> <p>4 Q. Why not?</p> <p>5 A. Because it would depend on the setting of</p> <p>6 when it is. I mean, to have something that's</p> <p>7 chronically inflamed would most likely be extruded,</p> <p>8 so some of the things are going to go with other</p> <p>9 things that you've mentioned.</p> <p>10 Q. Well, my question is, though, an implant of</p> <p>11 a TVT can cause chronic inflammation, right?</p> <p>12 A. It would depend on the situation. It</p> <p>13 would depend on the clinical presentation of the</p> <p>14 patient and whether that mesh were removed and</p> <p>15 whether it was resolved of their symptoms</p> <p>16 thereafter, and it would involve maybe looking at</p> <p>17 the pathology of that as well.</p> <p>18 Q. In other words, it can?</p> <p>19 A. It may. It depends on the circumstance.</p> <p>20 Not in all circumstances, but it may.</p> <p>21 Q. And the chronic pain can be associated with</p> <p>22 the implant of a TVT?</p> <p>23 A. It can be associated with any pelvic floor</p> <p>24 surgery.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q. But I'm asking a question specific to the</p> <p>2 TVT, so I'd like to limit our question and answer</p> <p>3 to that. So let me ask it again.</p> <p>4 The implant of a TVT can be associated with</p> <p>5 chronic pain, correct?</p> <p>6 A. It can.</p> <p>7 Q. And you would agree with me that there's a</p> <p>8 difference between postoperative pain and chronic</p> <p>9 pain?</p> <p>10 A. Yes.</p> <p>11 Q. And you would agree with me that the use of</p> <p>12 the word "transitory" has to do with what would</p> <p>13 typically be associated with postoperative pain,</p> <p>14 right?</p> <p>15 A. Transitory would refer to postoperative</p> <p>16 pain.</p> <p>17 Q. Transitory does not refer to chronic,</p> <p>18 long-term pain?</p> <p>19 A. No.</p> <p>20 Q. And what is postoperative pain?</p> <p>21 A. It's pain that occurs postoperatively.</p> <p>22 Q. And it usually disappears within a few days</p> <p>23 or sometimes a couple of weeks?</p> <p>24 MS. ROBINSON: Object to form.</p>	<p style="text-align: right;">Page 72</p> <p>1 MS. ROBINSON: Object to form.</p> <p>2 Q. -- correct?</p> <p>3 A. They -- the patient may think that.</p> <p>4 Q. Would you agree that there are few studies,</p> <p>5 if any, that track chronic long-term complications</p> <p>6 associated with the TVT?</p> <p>7 A. No. There's good data looking at long-term</p> <p>8 erosions and long-term -- and most people with</p> <p>9 erosions or extrusions are going to be the ones who</p> <p>10 have pain. Very few people who have had a</p> <p>11 carefully-implanted device will have long-term</p> <p>12 pain.</p> <p>13 Q. Name one article that tracks chronic</p> <p>14 long-term pain associated with the TVT.</p> <p>15 A. The original work by Olmstead, in his 90</p> <p>16 patients, he only had a single patient with issues.</p> <p>17 Look at the extrusion rates from the Cochrane</p> <p>18 review. And I'd have to look for specific names of</p> <p>19 other sources. But there are a variety of others</p> <p>20 that looked at erosions and extrusions and most of</p> <p>21 which would have pain.</p> <p>22 Q. Okay. But I didn't ask about erosions or</p> <p>23 extrusions. I asked you to name one study that</p> <p>24 tracked chronic long-term pain associated with the</p>
<p style="text-align: right;">Page 71</p> <p>1 A. It may, it may not.</p> <p>2 Q. Well, when it goes on for a period of</p> <p>3 sustained time, that interferes with the patient's</p> <p>4 quality of life well after the surgery, that's</p> <p>5 chronic pain, right?</p> <p>6 A. It could be, yes.</p> <p>7 Q. Well, do you have another definition for</p> <p>8 "chronic pain"?</p> <p>9 A. It could be, as you said, pain that affects</p> <p>10 quality of life, pain that affects their activities</p> <p>11 in some way.</p> <p>12 Q. And that can happen many years after the</p> <p>13 implant of the medical device, correct?</p> <p>14 A. Yes. But usually not. Usually, the pain is</p> <p>15 something that starts postoperatively and</p> <p>16 continues.</p> <p>17 Q. But it can be different from the pain that</p> <p>18 was postoperative, right?</p> <p>19 A. It usually is persistent.</p> <p>20 Q. Well, let's talk about the case of the</p> <p>21 TVT. You're aware of women that have been</p> <p>22 pain-free for years and then suddenly years later</p> <p>23 they develop chronic pain that they associate with</p> <p>24 the TVT implant --</p>	<p style="text-align: right;">Page 73</p> <p>1 TVT.</p> <p>2 A. I can't name one.</p> <p>3 MS. ROBINSON: Just to be fair, you're</p> <p>4 not asking him to look at his records,</p> <p>5 reports, or anything he has sitting in front</p> <p>6 of him, right?</p> <p>7 MR. WALLACE: He can look at anything</p> <p>8 he wants.</p> <p>9 MS. ROBINSON: Well, if he can look at</p> <p>10 anything he wants, you might want to take a</p> <p>11 few seconds and look at what he's got.</p> <p>12 MR. WALLACE: And just for the record,</p> <p>13 we're letting Dr. Zaslau review his</p> <p>14 materials in an attempt to answer the</p> <p>15 question as to whether or not there's one</p> <p>16 study that tracks long-term chronic pain</p> <p>17 with the TVT.</p> <p>18 THE WITNESS: I can't think of or see</p> <p>19 one that specifically refers to that for the</p> <p>20 long-term.</p> <p>21 MS. ROBINSON: You also have your</p> <p>22 studies in front of you as well.</p> <p>23 THE WITNESS: Right.</p> <p>24 MS. ROBINSON: And you've spent less</p>

<p style="text-align: right;">Page 74</p> <p>1 than a minute here looking through your 2 report. 3 MR. WALLACE: You get to ask him 4 questions later. 5 THE WITNESS: In the Tomaselli paper, 6 just looking at the long-term pain 7 complications of which the risks appear to 8 be very low, but can occur with minimally 9 invasive slings. 10 Q. What's the citation of that, please? 11 A. Tomaselli 2014. 12 Q. How far out is that study? 13 A. That is October 2014. 14 Q. No. I mean, how long did they follow the 15 patients for? 16 A. It's searched up to -- it's another 17 meta-analysis, but the review is up through June of 18 2014. Google databases up through June of 2014. 19 Also, the Unger paper from April of 2015 looked at 20 vaginal pain and groin pain and found a risk of 21 8 percent for vaginal pain and groin pain of 22 3.4 percent. 23 Q. How long did they follow those patients? 24 A. These are patients from June of 2003 to</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. And she knows that that pain may, in fact, 2 if things don't go as planned, could last the rest 3 of her life? 4 A. It can be long-term. 5 Q. Can you yourself remove all of the mesh 6 from a woman that has had a TVT implanted in her? 7 A. I wouldn't want to remove all of it. 8 Q. That's not what I'm asking. Can you? 9 A. Depends when it was implanted. 10 Q. What if it's been implanted for more than 11 six months? 12 A. It's tougher. 13 Q. What do you mean by that? 14 A. It will integrate within normal tissues. 15 Q. Have you ever removed the entirety of a TVT 16 from a woman? 17 A. No. 18 Q. And that would be a very morbid procedure, 19 wouldn't it? 20 A. No. It would be a very unnecessary 21 procedure. 22 Q. Let's -- not disputing "necessary" right 23 now. 24 You don't think it would be morbid at all?</p>
<p style="text-align: right;">Page 75</p> <p>1 December of 2013, and the follow-up was -- the 2 median time is about 18 months. 3 Q. So the median follow-up is about a year and 4 a half? 5 A. Yes. 6 Q. What qualifies as a long-term study? 7 A. We like to see more than five years of data. 8 Q. That doesn't qualify as a long-term study, 9 does it? 10 A. No. 11 Q. So in other words, that article, though you 12 have said it follows some back pain and groin pain, 13 it doesn't qualify as a long-term study following 14 chronic pain associated with the TVT even under 15 your definition, right? 16 A. Um-hmm. 17 Q. When you say "um-hmm," you mean you agree 18 with me? 19 A. Yes. 20 Q. Thank you. When you counsel a patient that 21 is about to be implanted with a TVT, do you tell 22 her that she may have persistent pain with 23 intercourse? 24 A. Yes.</p>	<p style="text-align: right;">Page 77</p> <p>1 A. I didn't say it wouldn't be morbid. I said 2 it wouldn't be necessary. 3 Q. Putting aside whether or not you believe 4 it's necessary as a physician, would removal of the 5 entire TVT be a morbid procedure? 6 A. It depends how it was placed. 7 Q. Could it be more morbid than an autologous 8 sling, would you call morbid? 9 A. It could be as morbid as an autologous 10 sling. Autologous slings can be very difficult to 11 remove. 12 Q. I'm talking about the -- removing the 13 fascia from the abdomen. Do you follow me? 14 A. No. 15 Q. Let me back up, because I took a step that 16 perhaps we can deal with. 17 My -- let's go back to my simple question. 18 Even though you've never removed the entirety of a 19 TVT from a woman and disagree as to whether or not 20 that would be necessary, would you agree with me 21 that it is a procedure that would require 22 significant dissection? 23 A. It could require significant dissection. 24 Q. Of what?</p>

<p style="text-align: right;">Page 78</p> <p>1 A. Of the tissue where it was placed.</p> <p>2 Q. Using what tools?</p> <p>3 A. Standard surgical equipment.</p> <p>4 Q. Like Metzenbaum scissors, for example?</p> <p>5 A. Right.</p> <p>6 Q. So, in other words, you literally have to</p> <p>7 try to cut it out, but when you're cutting it out,</p> <p>8 you're taking tissue with it?</p> <p>9 A. Well, it's hard to dissect because it's</p> <p>10 grown into the tissues.</p> <p>11 Q. So you're taking tissue with it when you're</p> <p>12 using these Metzenbaum scissors, right?</p> <p>13 MS. ROBINSON: Object to form. Asked</p> <p>14 and answered.</p> <p>15 A. You're taking tissue with it.</p> <p>16 Q. And that's undesirable?</p> <p>17 A. It may or may not be desirable. It depends</p> <p>18 on what the patient's complaining of or what the</p> <p>19 problem is.</p> <p>20 Q. Well, you'll agree with me that cutting into</p> <p>21 a woman like that is not something that you would</p> <p>22 do lightly?</p> <p>23 A. Cutting in to do what, to remove an implant?</p> <p>24 Q. Correct.</p>	<p style="text-align: right;">Page 80</p> <p>1 another area of extrusion later, for other reasons,</p> <p>2 such as being postmenopausal, being a smoker,</p> <p>3 having atrophy. So they can have an erosion at</p> <p>4 another time, from another area that wasn't a</p> <p>5 problem before then, but then became a problem</p> <p>6 years later.</p> <p>7 Q. Do you tell women that they may have to have</p> <p>8 multiple -- or that they may have multiple erosions</p> <p>9 and multiple surgeries?</p> <p>10 A. I tell people they need to follow up</p> <p>11 annually so we can assess them and see what they</p> <p>12 have that's going on.</p> <p>13 Q. But that doesn't answer my question.</p> <p>14 Do you tell women that they may have</p> <p>15 multiple erosions and multiple surgeries?</p> <p>16 A. It does answer your question, because you</p> <p>17 have to see what they have that's going on to know</p> <p>18 what to do for them. That's implied, is that they</p> <p>19 had surgery, they could have problems that require</p> <p>20 additional surgery or surgeries.</p> <p>21 Q. Again, I'm going to make my question even</p> <p>22 more simple: Do you when you're consenting a</p> <p>23 woman that's about to be implanted with</p> <p>24 polypropylene mesh tell her that she may have</p>
<p style="text-align: right;">Page 79</p> <p>1 A. It's a very straightforward thing when it's</p> <p>2 done for the right reasons, to remove what mesh</p> <p>3 needs to be removed.</p> <p>4 Q. Have you ever seen a woman erode in one area</p> <p>5 of the vaginal wall and you remove that mesh, and</p> <p>6 then she has an erosion in another place later?</p> <p>7 A. Sure. You can have that, yes.</p> <p>8 Q. So when you just gave your answer that you</p> <p>9 only remove what's necessary, how do you know that?</p> <p>10 A. You have to follow them and see. It depends,</p> <p>11 again, on why you're removing the mesh. Why are we</p> <p>12 removing this person's mesh that you're talking</p> <p>13 about? Is it eroded? Is it extruded? Is it pain?</p> <p>14 What are we removing it for?</p> <p>15 Q. What do you remove mesh for?</p> <p>16 A. All the reasons that I just said to you. So</p> <p>17 someone's mesh is extruded, the easiest thing to do</p> <p>18 is to remove the extruded portion of it and follow</p> <p>19 them and see.</p> <p>20 Q. Have you always -- let me -- I'm sorry.</p> <p>21 Are you done with your answer?</p> <p>22 A. No.</p> <p>23 Q. Go right ahead.</p> <p>24 A. So that doesn't mean they can't have</p>	<p style="text-align: right;">Page 81</p> <p>1 multiple erosions that require multiple surgeries,</p> <p>2 yes or no?</p> <p>3 A. Yes. I tell them that they will require --</p> <p>4 that they can require multiple procedures down the</p> <p>5 road.</p> <p>6 Q. Do you tell them that they may have multiple</p> <p>7 erosions?</p> <p>8 A. I don't tell them that they'd have multiple</p> <p>9 erosions. I tell them that they can have erosion</p> <p>10 or erosions.</p> <p>11 Q. Do you tell them that they may be on chronic</p> <p>12 pain medication for the rest of their lives?</p> <p>13 A. No. I tell them that they may have chronic</p> <p>14 pain, and that pain -- they may have pain, and that</p> <p>15 pain may be acute or it may persist and be chronic,</p> <p>16 and they may require other therapies for that.</p> <p>17 Q. You agree that chronic pain is challenging</p> <p>18 to treat?</p> <p>19 A. Yes.</p> <p>20 Q. And you would agree with me that improving</p> <p>21 someone's baseline even 30 percent is sometimes a</p> <p>22 good outcome?</p> <p>23 A. That's the goal of giving people narcotics,</p> <p>24 to improve them by 30 percent. That's the</p>

<p style="text-align: right;">Page 82</p> <p>1 definition of pain improvement.</p> <p>2 Q. And you would agree with me that they're</p> <p>3 still missing 70 percent improvement even with</p> <p>4 narcotics?</p> <p>5 A. It depends on the other situation. There's</p> <p>6 multiple reasons why a person can have pain.</p> <p>7 Q. I'm just trying to get you to agree with</p> <p>8 some simple math.</p> <p>9 A. I'm not understanding where you're getting</p> <p>10 the simple math from.</p> <p>11 Q. You're improving someone's -- your</p> <p>12 understanding of the reason why pain medications</p> <p>13 are given is to improve someone's baseline of pain</p> <p>14 30 percent, and if that happens, that is a good</p> <p>15 outcome, correct?</p> <p>16 MS. ROBINSON: Object to form.</p> <p>17 Misstates his testimony.</p> <p>18 A. That is the goal. We'd like to improve them</p> <p>19 more than 30 percent.</p> <p>20 Q. So if they only improve 30 percent, they</p> <p>21 still have 70 percent to go?</p> <p>22 A. It may not be possible to obtain that.</p> <p>23 Q. And you have seen women that are being</p> <p>24 treated for chronic pain that is associated with</p>	<p style="text-align: right;">Page 84</p> <p>1 is another medication that's used to treat chronic</p> <p>2 pain?</p> <p>3 A. Yes, it is.</p> <p>4 Q. In women that have mesh implants, right?</p> <p>5 A. These are all things that have been used,</p> <p>6 but most people that I come across don't have</p> <p>7 that and are easily fixed of their chronic pain.</p> <p>8 Q. I understand that you're a successful</p> <p>9 doctor, but you would agree with me that you've</p> <p>10 also seen women that are being treated with these</p> <p>11 drugs?</p> <p>12 A. Initially, before they come to me, yes.</p> <p>13 Q. But you're not saying that it's</p> <p>14 inappropriate to try to use these things to manage</p> <p>15 chronic pain or anything?</p> <p>16 A. Yeah. I think you need to find out why they</p> <p>17 have chronic pain. You need to figure out why --</p> <p>18 treating pain only gets rid of the pain. We need</p> <p>19 to know what the source of the pain is.</p> <p>20 Q. You yourself have used Elavil?</p> <p>21 A. I have.</p> <p>22 Q. There are side effects associated with that?</p> <p>23 A. I prescribe Elavil, yes, if that's what you</p> <p>24 mean, yes.</p>
<p style="text-align: right;">Page 83</p> <p>1 mesh that use tramadol?</p> <p>2 A. I've seen people use tramadol, yes.</p> <p>3 Q. And do you know that tramadol is used by NFL</p> <p>4 players to treat their pain after games?</p> <p>5 A. I don't know what NFL players use to treat</p> <p>6 their pain.</p> <p>7 Q. While we're sitting here in Morgantown, do</p> <p>8 you know whether or not the Mountaineers use --</p> <p>9 players use tramadol after games?</p> <p>10 A. I don't know that.</p> <p>11 Q. Would it surprise you to learn that that's a</p> <p>12 commonly prescribed pain medication that's used for</p> <p>13 those players that undergo those collisions?</p> <p>14 MS. ROBINSON: Object to form.</p> <p>15 A. It wouldn't surprise me, and it wouldn't</p> <p>16 concern me. It doesn't relate to me.</p> <p>17 Q. But you would believe that there are big</p> <p>18 side effects associated with chronic pain</p> <p>19 medication?</p> <p>20 A. There are.</p> <p>21 Q. And that's something you want to avoid, if</p> <p>22 at all possible, right?</p> <p>23 A. You'd like to, yeah.</p> <p>24 Q. So for example, you're aware that Neurontin</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. Have you ever prescribed it to a woman with</p> <p>2 a mesh implant?</p> <p>3 A. I have not.</p> <p>4 Q. And you've seen women go back to Neurontin,</p> <p>5 for example. That's a medication that has some</p> <p>6 side effects, right?</p> <p>7 A. Sure. These all do. But I don't routinely</p> <p>8 give any of these medicines to these people with</p> <p>9 chronic mesh pain.</p> <p>10 Q. Are you saying that a doctor that tries to</p> <p>11 do that for a patient that is suffering pain,</p> <p>12 chronic pain, is not following the standard of</p> <p>13 care?</p> <p>14 A. That's not a standard-of-care issue. It's a</p> <p>15 judgment call. Their judgment is they want to</p> <p>16 treat pain with pain medicines. Another way of</p> <p>17 treating their pain would be to go to what the</p> <p>18 source might be, to a good physical exam,</p> <p>19 urodynamics, if necessary, and see if that pain is</p> <p>20 reproducible, and then there are certainly surgical</p> <p>21 options that can be performed.</p> <p>22 Q. You believe that depression can come about</p> <p>23 as a result of chronic pain, right?</p> <p>24 A. It can go either way. You can have pain</p>

<p style="text-align: right;">Page 86</p> <p>1 that causes depression and depression that causes</p> <p>2 pain.</p> <p>3 Q. And you've described that as a vicious</p> <p>4 cycle?</p> <p>5 A. Yes.</p> <p>6 Q. Do you tell your clients that they may</p> <p>7 have -- that may happen to them as a result of a</p> <p>8 TVT implant?</p> <p>9 A. No. Because they shouldn't have chronic</p> <p>10 pain from this. I tell them that they certainly</p> <p>11 may have pain, but again, you're following them</p> <p>12 regularly, so you'll know if something has changed</p> <p>13 in them in their postoperative visits.</p> <p>14 Q. Would you agree with me that once somebody</p> <p>15 starts taking medicine like that, we've described,</p> <p>16 that there are some things that happen to them</p> <p>17 medically that you just cannot explain?</p> <p>18 A. I don't know what you mean by that.</p> <p>19 Q. Well, that's your testimony before. So</p> <p>20 that's what you've said before.</p> <p>21 A. Well, I don't know the context that it was</p> <p>22 said in. What was the question? What was the</p> <p>23 situation?</p> <p>24 Q. Let me -- I can go there, if we need to, but</p>	<p style="text-align: right;">Page 88</p> <p>1 explained.</p> <p>2 Q. And we want to avoid synthetic things like</p> <p>3 medicine when we can?</p> <p>4 A. Synthetic things?</p> <p>5 Q. Well, medicine -- the medicine that we've</p> <p>6 been talking about is manmade.</p> <p>7 A. Right.</p> <p>8 Q. And we want to avoid foreign bodies when we</p> <p>9 can?</p> <p>10 A. I don't know about that.</p> <p>11 Q. Why not?</p> <p>12 A. What do you mean by "foreign bodies"?</p> <p>13 Q. Well, you know that the body itself, when</p> <p>14 it's implanted with anything or we take a drug,</p> <p>15 there's a foreign body response?</p> <p>16 A. The same thing happens when you implant a</p> <p>17 piece of your own body into it.</p> <p>18 Q. So you think that synthetic is preferable to</p> <p>19 a nonsynthetic?</p> <p>20 A. In what context? You talked to me before</p> <p>21 about medicines, like Elavil and tramadol, and now</p> <p>22 you're talking about something synthetic. So I</p> <p>23 don't know what you mean by synthetic as a</p> <p>24 medicine, as opposed to not taking a medicine, or</p>
<p style="text-align: right;">Page 87</p> <p>1 let me try to short-circuit it, given our limited</p> <p>2 time frame.</p> <p>3 You've said before once people -- I'll take</p> <p>4 whether or not you've said it before out of it.</p> <p>5 I'll just ask you more directly: Once people start</p> <p>6 taking chronic -- I'm sorry, pain medication for</p> <p>7 long-term chronic pain, there are sometimes things</p> <p>8 that happen to them medically that are not readily</p> <p>9 explainable?</p> <p>10 MS. ROBINSON: Object to form.</p> <p>11 A. Yeah. Like I said, I don't know the context</p> <p>12 of where that's coming from.</p> <p>13 Q. Do you recall saying in the Edwards</p> <p>14 deposition that with medication there can be</p> <p>15 idiosyncratic effects that happen that cannot be</p> <p>16 explained?</p> <p>17 A. Yes.</p> <p>18 Q. Do you know why you said that?</p> <p>19 A. People can have -- idiosyncratic in medicine</p> <p>20 implies that if something has happened to them that</p> <p>21 is unexplainable, maybe they have a change in their</p> <p>22 vision, maybe they have a new onset of muscle pain</p> <p>23 in muscles that they have never had pain in, so</p> <p>24 they can have responses or reactions that are not</p>	<p style="text-align: right;">Page 89</p> <p>1 synthetic in another context? I don't know what</p> <p>2 you're asking me.</p> <p>3 Q. Would you agree with me that it's more</p> <p>4 desirable to try to avoid taking medicines like</p> <p>5 those we've just described, for example, Neurontin,</p> <p>6 Elavil, perhaps even oxycodone, right?</p> <p>7 A. Yes.</p> <p>8 Q. Those are all manmade products?</p> <p>9 A. Um-hmm.</p> <p>10 Q. You said earlier that you removed -- if I</p> <p>11 understood you correctly, approximately 200 slings</p> <p>12 since you've been counting?</p> <p>13 A. Yes.</p> <p>14 Q. I thought you said in Edwards -- and maybe</p> <p>15 the numbers have changed since then -- that it was</p> <p>16 about 75?</p> <p>17 A. We're close to that. My gynecology</p> <p>18 colleague has -- we've done some together, so I've</p> <p>19 looked at the patients that he's treated since, you</p> <p>20 know, we worked together on some cases. I'm</p> <p>21 involved in his, and he's involved in mine. So</p> <p>22 within the bulk of us, we're probably close to 200.</p> <p>23 Q. How many of those are slings compared</p> <p>24 to prolapses.</p>

<p style="text-align: right;">Page 90</p> <p>1 A. Most of them are slings. Very few of them 2 are prolapse. 3 Q. Why is that? 4 A. Slings more commonly performed in terms of a 5 procedure than a Prolift -- a prolapse case. 6 Q. How many of those 200 were your implants? 7 A. Two of them were, maybe three or so, but 8 really, less than a handful. 9 Q. How do you know that? 10 A. Because they were the only cases I did. 11 They had surgery somewhere else. 12 Q. As you sit here -- and I'm not going to ask 13 you the names -- but as you sit here, do you know 14 the names of the individuals that had to have their 15 sling removed -- 16 A. No. 17 Q. -- that were your patients? 18 A. No. 19 Q. So why do you come up with the two or 20 three? 21 A. Because it's a very, very small number of 22 people over the years that I had to remove their 23 slings. 24 Q. In other words, so approximately 197 or 198</p>	<p style="text-align: right;">Page 92</p> <p>1 A. Well, this is an expected complication of 2 pelvic floor surgery. It's something that should 3 have been discussed with them by any person who 4 does pelvic floor surgery. 5 Q. So if the rates of complications -- you 6 realize -- let me back up for a second. 7 You realize that there are many physicians, 8 in fact, lots of physicians besides you that 9 disagree with your definition of an "adverse event" 10 and report removals? 11 MS. ROBINSON: Object to form. 12 Q. Right? 13 A. People have different practice ways. 14 Q. Well, you'll agree with me that there are 15 many physicians because -- 16 A. I don't know who reports what and how -- and 17 what the individual practices are, of who reports 18 things. 19 Q. So the only reporting that should be done 20 should be in connection with the study is your 21 opinion? 22 A. I think it should be done in connection 23 with a study, yes. Unless there's an egregious 24 issue that had gone on with a procedure that was</p>
<p style="text-align: right;">Page 91</p> <p>1 of the 200 are not implants of yours? 2 A. That's right. 3 Q. When you remove those slings, do you report 4 them as adverse events? 5 A. No. 6 Q. Why not? 7 A. Because very few of them were extrusions, so 8 there's no reason to report that. 9 Q. The few that were extrusions, did you report 10 those as adverse events? 11 A. No. Because those are expected 12 complications of the procedure. The other ones 13 were removed either because patients wanted them 14 removed, or they had obstructive voiding symptoms, 15 or wanted some relief of whatever's going on with 16 them, be it dyspareunia or such. 17 Q. Well, when someone has dyspareunia and has 18 to have a mesh removed, that's an adverse outcome 19 of a procedure, correct? 20 A. No. 21 Q. You don't think so? 22 A. No. It is an expected -- 23 Q. Have you asked any of those women whether 24 they think that's a good thing or a bad thing?</p>	<p style="text-align: right;">Page 93</p> <p>1 untoward and unexpected in any imagination of how 2 it should be performed. 3 Q. You used the word "untoward" in prior 4 testimony as well. 5 What do you mean by that? 6 A. If you put a TVT trocar in and you 7 perforate someone's stomach, you should be nowhere 8 near someone to be able to do that, where you 9 perforate an organ that's nowhere in your surgical 10 field. 11 Q. Wouldn't it be important for the public 12 and/or physicians and ultimately patients to know 13 that the rates of complications are high? 14 A. Who said they were high? 15 Q. Or low? 16 A. Well, we know that they're low. We've seen 17 that through the literature. 18 Q. So the sole basis, besides what's in your 19 hands, meaning your own experience, that the 20 complications are low -- actually, I'm going to ask 21 the question a better way. 22 You rely on the literature and your own 23 experience to conclude that the complications 24 associated with the TVT are low, correct?</p>

<p style="text-align: right;">Page 94</p> <p>1 A. I also rely on presentations of the AUA, 2 Webinars from other societies, position statements 3 by societies. 4 Q. So if physicians believe that you should be 5 reporting removals for dyspareunia as an adverse 6 event, you would disagree with them? 7 A. I didn't say I would disagree with them. If 8 there's a national standard that has been accepted 9 and put in place by a specialty board, then we all 10 should follow the same standards. 11 Q. Do you? 12 A. I do not report them. 13 Q. Do you follow the standards? 14 A. Yes. 15 Q. You're certain? 16 A. I follow the standards. 17 Q. Has it been your practice in all 200 or so 18 of those surgeries to send what you've removed to 19 pathology? 20 A. Yes. 21 Q. And if I understand what you've said before 22 about that, you see localized chronic inflammation 23 when you get it back? 24 A. Yeah. Well, the vast majority have</p>	<p style="text-align: right;">Page 96</p> <p>1 A. That undue tensioning can be associated with 2 pain, yes. 3 Q. And that's because of scarring? 4 A. It may. It may also be other causes as 5 well. 6 Q. When you look at these pathological 7 examples, do you see evidence of foreign bodies? 8 A. Some -- what do you mean by "foreign body"? 9 I mean, mesh is a foreign body. 10 Q. What else do you see? 11 A. It depends what the specimen is looked for. 12 Oftentimes I'll see evidence of chronic inflamma- 13 tion, multinucleated giant cells, areas of fibro- 14 blast infiltration. Very few, if any, had any acute 15 inflammatory process, neutrophils and such. And 16 some, depending upon the pathologist, may show the 17 presence of polarizing tissue or polarizing fibers. 18 Q. And you've seen tissue that is wound up in 19 the mesh? 20 A. I've seen tissue that's incorporated in the 21 mesh. 22 Q. You don't test for degradation? 23 A. Degradation, why? 24 Q. No. I just asked, do you test for</p>
<p style="text-align: right;">Page 95</p> <p>1 localized chronic inflammation. 2 Q. And you see some fibrotic bridging? 3 A. We see some fibrosis. 4 Q. What's the difference? 5 A. Fibrosis is a scar formation as a result of 6 fibroblast infiltration of tissue. Breaching may 7 be such that the pore size of the mesh will shrink 8 in a way to create more of a bridge of scar. 9 Q. And you've seen that in some of these 10 pathology samples that -- where you've removed the 11 mesh, right? 12 A. I haven't seen that, no. 13 Q. You've seen fibrosis, though? 14 A. I've seen fibrosis. 15 Q. And the scarring, you believe, that's 16 undesirable? 17 A. No. Scarring is a part of healing. 18 Fibrosis is a part of healing. 19 Q. Well, you have said before, though, that 20 with respect to tensioning, for example, that 21 getting scarring as a result of too much tension is 22 undesirable and can cause pain, right? 23 A. Yes. 24 Q. So you agree with the statement I just made?</p>	<p style="text-align: right;">Page 97</p> <p>1 degradation? 2 A. We don't specifically test for it. 3 Q. Have you ever had to tug on the mesh to get 4 it out when you're doing removal? 5 A. I'm trying to dissect it to get down to 6 where you think it is. Oftentimes there's a lot 7 of scar depending upon where it was placed and who 8 placed it. And we try not to tug on it. We try to 9 dissect it as free and as easily as we can. 10 Q. Would you be surprised to know that even 11 some urologists that are even more experienced than 12 you have had to literally wrap their hands around 13 the a piece of mesh and tug on it to get the rest 14 of it out? 15 MS. ROBINSON: Object to form. 16 A. I would hope they wouldn't do that. There's 17 no reason to do that. I wouldn't be surprised that 18 they would do that, but it's not necessary. 19 Q. Some have done that, right? 20 A. I haven't heard of anyone who has, but since 21 you say, I'm sure somebody has, and there's no 22 reason for them to do it. 23 Q. Can you guarantee a woman that you can get 24 all of her mesh out?</p>

<p style="text-align: right;">Page 98</p> <p>1 A. No. And there's no reason to.</p> <p>2 Q. Is it foreseeable that someone with a TVT</p> <p>3 mesh in them may need to have other surgeries in</p> <p>4 that area?</p> <p>5 A. Sure.</p> <p>6 Q. And, in fact, a woman may present to you as</p> <p>7 healthy and a perfect candidate for the TVT on</p> <p>8 April 1st of 2016, but by December 31st of 2016,</p> <p>9 she may be in poor health and may need surgery in</p> <p>10 the area in which that TVT was implanted?</p> <p>11 A. I don't understand what you're referring to.</p> <p>12 They shouldn't need surgery there. We assume</p> <p>13 they've had a good exam, they have no other</p> <p>14 prolapse and no other findings, that they shouldn't</p> <p>15 need any other surgery.</p> <p>16 Q. But it's perfectly possible that they might?</p> <p>17 A. I'd have to know the situation. I don't</p> <p>18 know what we would possibly be going in there for.</p> <p>19 Q. Do you use the TVT mechanical-cut or the</p> <p>20 TVT laser-cut mesh?</p> <p>21 A. I use them both.</p> <p>22 Q. Do you make a specific request for one over</p> <p>23 the other?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. Okay. So you personally have not seen a</p> <p>2 different need for it, but you would agree with me</p> <p>3 that Ethicon received information, and as a result</p> <p>4 of receiving that information, it concluded that</p> <p>5 there was a clinical need for laser-cut mesh?</p> <p>6 MS. ROBINSON: Object to form.</p> <p>7 A. I don't know that there's a true clinical</p> <p>8 need. It doesn't make sense to me that --</p> <p>9 Q. So in other words, there's no need for</p> <p>10 laser-cut mesh?</p> <p>11 A. I don't think there's a need for it.</p> <p>12 Q. So Ethicon is just making this up?</p> <p>13 A. I didn't say they're making it up. I just</p> <p>14 said that I don't think there's a need for it. I</p> <p>15 haven't seen a difference in my patients that I can</p> <p>16 say, "Wow, I'm so happy that I used laser-cut mesh</p> <p>17 and not mechanically-cut mesh."</p> <p>18 Q. Well, you would expect Ethicon to make its</p> <p>19 decisions based upon good medicine and science,</p> <p>20 right?</p> <p>21 A. I would expect them to have good reason for</p> <p>22 the things that they do.</p> <p>23 Q. So if they concluded that there was a</p> <p>24 clinical reason to come up with a TVT laser cut,</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. And how do you know whether or not you're</p> <p>2 using a mechanical-cut versus a laser-cut mesh?</p> <p>3 A. Well, I actually didn't know the difference</p> <p>4 until these litigation cases have brought this into</p> <p>5 the world. I've had no issues with -- in knowing</p> <p>6 the difference in either of them, nor do I think it</p> <p>7 has any clinical relevance.</p> <p>8 Q. Well, do you disagree with Ethicon?</p> <p>9 A. I don't see any difference in either of the</p> <p>10 two.</p> <p>11 Q. Well, I'm asking you: Do you disagree with</p> <p>12 Ethicon?</p> <p>13 MS. ROBINSON: Object to form.</p> <p>14 A. With regard to what?</p> <p>15 Q. Well, Ethicon felt that there was a clinical</p> <p>16 need for a laser-cut mesh, didn't it?</p> <p>17 MS. ROBINSON: Object to form. If you</p> <p>18 know the answer to it.</p> <p>19 A. I don't know that they -- I know that they</p> <p>20 have -- that information had been given to them,</p> <p>21 that, you know, maybe this should be considered,</p> <p>22 and obviously they did. But it wouldn't have</p> <p>23 mattered to me. I've not seen a difference or a</p> <p>24 need for it.</p>	<p style="text-align: right;">Page 101</p> <p>1 you'd have to trust their judgment?</p> <p>2 A. I would hope they would make good decisions.</p> <p>3 Q. And do you know how many TVT mechanical-cut</p> <p>4 meshes you've implanted in your career?</p> <p>5 A. Well, the changeover is about 2007 or 2008,</p> <p>6 so I don't know, 200 or so.</p> <p>7 Q. Do you know how many TVT laser-cut you've</p> <p>8 implanted in your career?</p> <p>9 A. In 2007-2008 to the present, probably 150 or</p> <p>10 so.</p> <p>11 Q. As you sit here today, do you believe that</p> <p>12 laser-cut is the only type of TVT mesh that is</p> <p>13 offered, or is mechanical-cut still available?</p> <p>14 A. No. I think that mechanical is still</p> <p>15 available.</p> <p>16 Q. Have you ever been told by Ethicon that</p> <p>17 there are different risk profiles for the TVT</p> <p>18 mechanically-cut versus the TVT laser-cut?</p> <p>19 A. What do you mean by "risk profile"?</p> <p>20 Q. That the TVT mechanical-cut comes with</p> <p>21 different risks than the TVT laser-cut?</p> <p>22 A. Risks of what?</p> <p>23 Q. Risks to the patient.</p> <p>24 A. No.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. Has anyone ever told you that the TVT 2 mechanical-cut mesh can rope? 3 A. Yes, I've heard that. 4 Q. From who? 5 A. From review of the literature. 6 Q. Have you ever observed that? 7 A. Yes. 8 Q. When? 9 A. When we do different experiments with the 10 mesh ex vivo. So when we pull on the mesh by 11 itself, be it mechanically-cut or laser-cut, it'll 12 rip and tear, and it won't regain its normal form. 13 And the pore size will certainly be distorted. 14 But, interestingly, when we do the same thing with 15 the plastic sheath over it, we can't move the mesh 16 despite how hard we pull. We've actually even 17 looked with an operative telescope at patients 18 that we finished doing the TVT on to see if there 19 is any evidence of fiber loss or any change in 20 what I think the mesh should look like, and I've 21 never seen any. 22 Q. Have you published the results of that 23 testing? 24 A. We did not.</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. By whom? 2 A. By review of the literature. 3 Q. And have you ever been told that the TVT 4 mechanical-cut mesh can release -- that there can 5 be particle loss associated with the mechanical-cut 6 mesh? 7 A. I've read that. 8 Q. And my understanding is you don't believe 9 that has clinical significance? 10 A. I don't think it does. 11 Q. You would agree with me, though, that it's 12 well-established in the scientific and medical 13 literature that particles that are of a foreign 14 body cause a foreign body response, correct? 15 A. When you say "foreign body," you're 16 referring to mesh as a foreign body, right? 17 Q. Correct. 18 A. So you're not referring to autologous 19 slings. That's a foreign body, too. It has no 20 blood supply, so they can cause a foreign body 21 reaction, too. 22 Q. You're not answering my question. I'm not 23 talking about autologous slings right now. I'm 24 talking about particle loss associated with the</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Where's the data to back up that claim? 2 A. It's personal experience and just bedside 3 teaching. 4 Q. So I just have to take your word for it? 5 A. That's correct. 6 Q. There's no data that I can look at or cross 7 examine to test the veracity of that statement? 8 A. To test the veracity of what I just said 9 about pulling them and rip -- and pulling them 10 apart? Well, certainly, you can look at what your 11 own experts and the pictures that they have 12 provided about stretching mesh ex vivo and you'd 13 see particle movement and flaking of that, 14 certainly. 15 Q. I'm talking about what you did, though. 16 A. I don't know that anyone else has done that. 17 But -- 18 Q. So it's you and your partners looking 19 right after a surgery before there's been mesh 20 ingrowth? 21 A. Right. 22 Q. Have you ever been told that TVT mesh can 23 curl? 24 A. I've been told that, yes.</p>	<p style="text-align: right;">Page 105</p> <p>1 mechanical-cut mesh. Let's stick to that for a 2 moment, just to finish this line of questioning. 3 You would agree with me that you've seen 4 reports of that in the literature? 5 A. Yes. 6 Q. And you would agree with me, given your 7 hefty reliance list, that you've also seen some 8 Ethicon documents on that? 9 A. Yes. 10 Q. And you still conclude, even after reviewing 11 those documents and that literature, that there is 12 no clinical relevance to that issue? 13 A. That's correct. 14 Q. And you would agree with me that the 15 particle loss that Ethicon describes, as well as 16 the literature, is from the TVT mesh itself -- 17 MS. ROBINSON: Object to the form. 18 Q. -- which is a foreign body? 19 A. That the particle loss is from the TVT? 20 Q. Correct. It's pretty well-accepted, right? 21 A. Yeah. 22 Q. I'm not trying to start a disagreement 23 between us. I'm just trying to get through this. 24 And you would agree with me that your</p>

<p style="text-align: right;">Page 106</p> <p>1 opinion differs from other physicians about the 2 clinical relevance of particle loss? 3 A. It differs. 4 Q. In what way? 5 A. Well, experts believe that this can be a 6 source of pain for patients, and other associated 7 symptoms that are supposedly debilitating and 8 lifelong and very problematic. 9 Q. And you would agree with me that Ethicon 10 itself concluded, at least in part, that the 11 clinical basis for coming up with the laser-cut 12 mesh was the particle loss associated with the 13 mechanical-cut mesh? 14 MS. ROBINSON: Object to form. 15 A. That may have been a consideration for them, 16 but -- 17 Q. In fact, you've seen documents that suggest 18 that? 19 A. Yeah. 20 Q. And your reliance list. Even you've seen 21 Ethicon documents that suggest that's a clinical 22 basis for changing the laser-cut mesh, right? 23 A. It very well could be. 24 Q. I mean, you're not going to disagree with a</p>	<p style="text-align: right;">Page 108</p> <p>1 right? 2 A. Yes. 3 Q. And as I understand it, given your 4 academic setting or at least your setup now at 5 the university, sales representatives don't have 6 unfettered access, do they? Right? 7 A. They do have significant access to us, yes. 8 Q. They have access to you? 9 A. Yes. 10 Q. Have you ever testified differently? 11 A. They have access to us, but in different 12 settings. In other words, industry or 13 product-based reps can come to the operating room. 14 They always have been able to, and they still are 15 able to. 16 Q. So you see Ethicon representatives actually 17 in the operating room at the university when a 18 TVT's being implanted? 19 A. We don't see them now. We don't see -- we 20 just don't see reps from them. I haven't seen an 21 Ethicon rep in years. 22 Q. Why not? 23 A. I don't know. But they are allowed to. We 24 have other device reps that are in the OR all the</p>
<p style="text-align: right;">Page 107</p> <p>1 document that you've seen that says that, right? 2 MS. ROBINSON: Object to form. Asked 3 and answered 100 times. 4 Q. Correct? 5 A. I have no other comments. 6 MR. WALLACE: Let's take a five-minute 7 break. 8 (Brief break at 1:41 p.m.) 9 (Back on at 1:44 p.m.) 10 BY MR. WALLACE: 11 Q. These Ethicon documents that we've been 12 discussing for the last several minutes about 13 particle loss and the clinical implications of 14 that, did Ethicon share those with you prior to 15 your being hired as an expert? 16 A. No. 17 Q. Were any internal Ethicon documents ever 18 shared with you prior to you being hired as an 19 expert? 20 A. No. 21 Q. So the Ethicon documents that you had access 22 to would include anything that was provided to you 23 in the instructions for use and anything that might 24 have been given to you by a sales representative,</p>	<p style="text-align: right;">Page 109</p> <p>1 time. 2 Q. I guess what I'm asking you is, what 3 information did you have from Ethicon up until the 4 time you were hired as an expert? 5 A. The IFU. 6 Q. What else? 7 A. Certainly, the -- our classic core 8 textbooks, articles, meetings that we've attended. 9 Q. Did you have textbooks from Ethicon? 10 A. No. The core textbooks of urology. 11 Q. Okay. I'm specifically asking you about 12 Ethicon documents. There are things that are 13 called slick sheets, are you familiar with those? 14 A. What sheets? 15 Q. Slick sheets. 16 A. What's that? 17 Q. Okay. The fact that you're asking about it 18 must mean that you don't have it. Those are 19 laminated instructions. 20 A. No. 21 Q. So Ethicon didn't give you those? 22 A. No. 23 Q. You basically had the instructions for use, 24 and that was the only document, per se, that was</p>

<p style="text-align: right;">Page 110</p> <p>1 given to you by Ethicon in connection with the TVT</p> <p>2 device, right?</p> <p>3 A. Yes.</p> <p>4 Q. In other words, you were never given the</p> <p>5 seven-year Prolene dog study, right?</p> <p>6 A. No.</p> <p>7 Q. You were never given PowerPoints, for</p> <p>8 example, that might have been put together on the</p> <p>9 concept of degradation of polypropylene?</p> <p>10 A. No.</p> <p>11 Q. None of that information was shared with</p> <p>12 you, right?</p> <p>13 A. That's correct.</p> <p>14 MS. ROBINSON: And just so the record's</p> <p>15 clear --</p> <p>16 Q. Let me finish, and then you can make it.</p> <p>17 And just to be clear, that information that</p> <p>18 is included on your reliance list was only provided</p> <p>19 to you after you agreed to testify on Ethicon's</p> <p>20 behalf?</p> <p>21 A. Yes.</p> <p>22 MS. ROBINSON: That was my question.</p> <p>23 You keep saying "never" and so forth.</p> <p>24 MR. WALLACE: I was going there.</p>	<p style="text-align: right;">Page 112</p> <p>1 warnings.</p> <p>2 A. Um-hmm.</p> <p>3 Q. Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. It says that the Prolene polypropylene mesh</p> <p>6 will not stretch significantly. Do you see that?</p> <p>7 A. Um-hmm.</p> <p>8 Q. In fact, you would agree with me that mesh</p> <p>9 shrinks?</p> <p>10 A. I don't know that it shrinks.</p> <p>11 Q. Well, you've said that hernia mesh shrinks,</p> <p>12 right?</p> <p>13 A. Yes.</p> <p>14 Q. What's the difference between the mesh</p> <p>15 that's used in Ethicon's hernia meshes and the TVT?</p> <p>16 A. Well, the data you're referring to is hernia</p> <p>17 meshes that were removed, so they determined that</p> <p>18 it contracted. But TVT mesh or vaginal mesh might</p> <p>19 behave differently.</p> <p>20 Q. Do you believe that the properties are</p> <p>21 different?</p> <p>22 A. Yes.</p> <p>23 Q. How?</p> <p>24 A. Well, hernia mesh is often thicker,</p>
<p style="text-align: right;">Page 111</p> <p>1 Can you mark this as an exhibit?</p> <p>2 (Deposition Exhibit No. 5 was marked for</p> <p>3 identification.)</p> <p>4 Q. You've been handed Exhibit 5. Do you</p> <p>5 recognize that as a set of instructions for use for</p> <p>6 the TVT?</p> <p>7 A. Yes.</p> <p>8 Q. And it's in various languages. Do you see</p> <p>9 that?</p> <p>10 A. Yes.</p> <p>11 Q. Is this what would come in the package?</p> <p>12 A. Yes. An instruction sheet comes in every</p> <p>13 package.</p> <p>14 Q. And the instructions provide</p> <p>15 contraindications and warnings, correct?</p> <p>16 A. It's supposed to.</p> <p>17 Q. Well, with respect to the TVT, it came with</p> <p>18 that, correct?</p> <p>19 A. I'm trying to find the English one. But</p> <p>20 it's supposed to.</p> <p>21 Q. If you look at the Bates number ending in</p> <p>22 383, and, actually, the page before it, 382 --</p> <p>23 A. Yes.</p> <p>24 Q. -- there's a list of contraindications and</p>	<p style="text-align: right;">Page 113</p> <p>1 other materials are used for it. It provides a</p> <p>2 different kind of support.</p> <p>3 Q. Well, let's talk about Ethicon hernia mesh.</p> <p>4 Ethicon hernia mesh, isn't that the same thing as a</p> <p>5 TVT in terms of the material?</p> <p>6 A. If it's polypropylene macropore and</p> <p>7 monofilament, then it should be the same.</p> <p>8 Q. Okay. But you -- so in other words, you</p> <p>9 have no scientific basis to disagree with me that</p> <p>10 the TVT mesh contracts in the same way that the</p> <p>11 hernia mesh does?</p> <p>12 A. There's other data that you can extrapolate,</p> <p>13 physical exam data, Q-tip testing, and how that</p> <p>14 doesn't result in a worsening of a patient's</p> <p>15 hypermobility after a TVT is placed looking out at</p> <p>16 a year, there's ultrasound data showing increase</p> <p>17 in visualization of the mesh because of hyperechoic</p> <p>18 particles of it that increase over time, suggesting</p> <p>19 that it doesn't contract, it probably remains the</p> <p>20 same, and it doesn't move, either.</p> <p>21 Q. So you don't believe that a TVT mesh, once</p> <p>22 incorporated into -- as it incorporates into the</p> <p>23 tissues contracts at all?</p> <p>24 A. As it incorporates in tissue, when placed</p>

<p style="text-align: right;">Page 114</p> <p>1 normally, when placed according to the IFU and also</p> <p>2 placed according to what a reasonable surgeon</p> <p>3 should know how to do in terms of dissection</p> <p>4 and being away from the urethra and following a</p> <p>5 normal tissue plane and placing it tension-free,</p> <p>6 then yes, it shouldn't change.</p> <p>7 Q. In other words, if it's put in properly, you</p> <p>8 do not believe that the TVT contracts?</p> <p>9 A. I don't think so.</p> <p>10 Q. Even when it's undergoing mesh incorporation</p> <p>11 with the tissues in the body?</p> <p>12 A. It shouldn't contract.</p> <p>13 Q. And yet, you still believe that hernia mesh</p> <p>14 contracts?</p> <p>15 A. Yes.</p> <p>16 Q. And you don't believe that the TVT Prolene</p> <p>17 mesh is the same kind of mesh that exists in the</p> <p>18 old hernia meshes at Ethicon?</p> <p>19 A. I'm not sure of the specifics of whether</p> <p>20 it's the same or not. I don't do hernia surgery.</p> <p>21 Q. What if they are?</p> <p>22 A. Then they are.</p> <p>23 Q. Does it change your opinion?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 116</p> <p>1 Q. What does "minimal tension" mean?</p> <p>2 A. Minimal tension means that the graft is</p> <p>3 placed without any other tissue or structure</p> <p>4 impeding it, so it's not creating pressure on</p> <p>5 another structure, such as the urethra or the</p> <p>6 vaginal wall.</p> <p>7 Q. That's a subjective measurement.</p> <p>8 A. It's subjective, yes.</p> <p>9 Q. And using the word "loosely" is also a</p> <p>10 subjective description, correct?</p> <p>11 A. That's right.</p> <p>12 Q. And if I understand your prior testimony</p> <p>13 correctly, you don't place the TVT laser-cut mesh</p> <p>14 any differently than you do the mechanical-cut</p> <p>15 mesh?</p> <p>16 A. That's right.</p> <p>17 Q. And you would tell me that it's also your</p> <p>18 testimony that whether or not it's laser-cut or</p> <p>19 mechanical-cut does not affect the tension?</p> <p>20 A. It does not.</p> <p>21 Q. So you disagree with Ethicon's own medical</p> <p>22 director on that?</p> <p>23 A. I don't think it has any difference in my</p> <p>24 practice.</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Do you believe that tensioning affects</p> <p>2 shrinkage?</p> <p>3 A. Placing something on tension that shouldn't</p> <p>4 be tensioned can have significant changes to</p> <p>5 outcome.</p> <p>6 Q. Do you believe Ethicon is responsible to</p> <p>7 tell physicians how to properly tension the device?</p> <p>8 A. They have.</p> <p>9 Q. So you believe that they properly instruct</p> <p>10 physicians on how to do that?</p> <p>11 A. I think their initial description of that</p> <p>12 was adequate, and I think the modifications that we</p> <p>13 have made from the original videos from 1998 and</p> <p>14 the original teachings of it have made it --</p> <p>15 created other opportunities for us to tension --</p> <p>16 Q. Who's "we"?</p> <p>17 A. "We" as in urologists who are -- and</p> <p>18 urogynecologists and the gynecologists from the</p> <p>19 publications, presentations.</p> <p>20 Q. What happens if the tension is not right?</p> <p>21 A. What does that mean by "not right"?</p> <p>22 Q. Too tight?</p> <p>23 A. Too tight, then you can have a whole host of</p> <p>24 symptoms in patients.</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. If the device is not tensioned correctly, do</p> <p>2 you believe that's the fault of the physician?</p> <p>3 A. Yes.</p> <p>4 Q. And you know that tension can cause</p> <p>5 scarring, and you want to avoid that because that</p> <p>6 can cause pain?</p> <p>7 A. Yes, it can.</p> <p>8 Q. Would you agree with me that overtightening</p> <p>9 is easy to achieve?</p> <p>10 A. Oh, yes.</p> <p>11 Q. Where is chronic pain listed in Exhibit 5?</p> <p>12 A. I don't see that it is.</p> <p>13 Q. It's not listed in the instructions for</p> <p>14 use that existed before 2015, right?</p> <p>15 A. Right.</p> <p>16 Q. And as an expert that's been hired by</p> <p>17 Ethicon to opine on the safety and efficacy of</p> <p>18 the TVT device, you would agree with me that the</p> <p>19 2015 version of the IFU was much more complete</p> <p>20 when it comes to listing the complications and</p> <p>21 warnings that may be relevant to the TVT device,</p> <p>22 right?</p> <p>23 MS. ROBINSON: Object to form.</p> <p>24 A. I'd say it's a more lengthy list of</p>

<p style="text-align: right;">Page 118</p> <p>1 complications. I'm not saying that it should or 2 should not have been in the original version. 3 Q. Does the original version list dyspareunia 4 as a risk? 5 A. No. 6 Q. Does it even use the word "dyspareunia"? 7 A. No. But that's understood. It's a pelvic 8 surgery, and any pelvic surgery can have those 9 risks. 10 Q. So you don't believe that a medical device 11 company is obligated to put in the risks that are 12 associated with this device? 13 A. The risks associated with that specific 14 device that are different from other devices and/or 15 other surgeries and ways that we do things. 16 Q. And you would agree with me that your 17 opinion is different from any other physician's on 18 that issue, correct? 19 A. I don't know that. 20 Q. You would agree with me that your opinion on 21 that issue is different than the standards that 22 apply to warnings, right? 23 A. No. 24 Q. You're not a warnings expert?</p>	<p style="text-align: right;">Page 120</p> <p>1 A. Because these -- the warnings that are 2 placed on us are warnings that are appropriate to 3 this particular device, that are germane to this 4 device. But there are other warnings that are not 5 listed that could occur with this surgery or any 6 other ones that are performed. 7 Q. And you realize that your testimony differs 8 from the standards that apply to warnings, right? 9 Because as a warnings expert that's been hired by 10 Ethicon, you've done your due diligence, naturally, 11 and have reviewed those standards, right? 12 A. Yes. 13 Q. And what are the standards? 14 A. There's a standard form when an IFU is put 15 together. There's material on sections that need 16 to be followed. But the material that's placed in 17 there is under the discretion of the company itself 18 with further conjunction. 19 Q. That's not true, is it? 20 A. What's not true? 21 Q. You are supposed to list all known risks. 22 That's what the standards require, right? 23 A. All known risks related to that product. 24 Q. So your definition that it has to be only</p>
<p style="text-align: right;">Page 119</p> <p>1 A. I am familiar with warnings, yes. 2 Q. But you're not a warnings expert? 3 A. Is it on my CV that I am? No. 4 Q. I don't see it. I'm asking you, you're not 5 a warnings expert, are you? 6 A. I'm knowledgeable about warnings. 7 Q. But are you a warnings expert, yes or no? 8 A. I can't answer that question. 9 Q. Why not? 10 A. I'm knowledgeable about warnings as they 11 pertain to me. 12 Q. Why can't you answer that question? 13 A. I can't answer that question. 14 Q. Have you been hired to opine on the warnings 15 in this case as a warnings expert or not? 16 A. Yes. 17 Q. You have? 18 A. Yes. 19 Q. You believe you have? 20 A. Um-hmm. 21 Q. And you believe that you're an expert with 22 respect to the Ethicon warnings? 23 A. Yes. 24 Q. Why?</p>	<p style="text-align: right;">Page 121</p> <p>1 related to that product is inaccurate, correct? It 2 does not match the standards? 3 A. No. 4 Q. You just said, Doctor, that all known risks 5 related to the product have to be listed. 6 A. That are specific to that product and not 7 other things that could be known by surgeons to do 8 other procedures. 9 Q. And what's the name of the standard that 10 you're citing to? 11 A. Citing to what? 12 Q. That requires that only risks relating to 13 that product? 14 A. That's the Blue Book for looking at the FDA 15 requirements. 16 Q. Death is listed with anesthesia, and that's 17 not unique to anesthesia. 18 A. Maybe. 19 Q. So do you want to change your testimony? 20 A. No. 21 Q. So if the standard that you believe exists 22 that in -- and controls this issue is different 23 than your testimony, would you amend your 24 testimony to reflect that of the standard?</p>

<p style="text-align: right;">Page 122</p> <p>1 A. If I'm told of other information, I 2 certainly would be happy to review it. 3 Q. Fair enough, Doctor. But what I'm getting 4 at is, if your testimony directly conflicts with 5 this standard, would you agree that the standard 6 controls? 7 MS. ROBINSON: Object to form. He's 8 asked and answered that question six times. 9 Q. He has not answered that question. And I'm 10 going to ask the court reporter to read it back 11 now, and ask you to restrict your comments. 12 Please read the question back. 13 (Record read.) 14 Q. Can you answer that question, yes or no? 15 A. I can't answer it yes or no. I need to 16 review what the standard is or what you're 17 referring to. 18 Q. Well, you cited the Blue Book. Are you 19 familiar with the Blue Book? 20 A. I've looked at it. 21 Q. And all I'm asking is if your testimony 22 conflicted with the Blue Book, would you or the 23 Blue Book control? 24 A. The Blue Book controls.</p>	<p style="text-align: right;">Page 124</p> <p>1 Q. And the adverse reaction that says "one or 2 more revision surgeries may be necessary to treat 3 these adverse reactions" is listed for the first 4 time in the 2015 IFU, correct? 5 A. That's correct. 6 Q. None of what I just read was in any prior 7 version of the instructions for use, correct? 8 A. That's right. 9 Q. You are aware, in connection with your 10 reliance list with documents, internal Ethicon 11 documents that state that fraying is a defect, 12 correct? 13 A. No. 14 Q. You haven't seen that? 15 A. No. 16 Q. Have you seen any documents concluding that 17 mesh degrades? 18 A. No. 19 Q. So you haven't seen any internal Ethicon 20 documents indicating that mesh degrades? 21 A. No. 22 Q. Did you ask for any? 23 A. No. 24 Q. Why not?</p>
<p style="text-align: right;">Page 123</p> <p>1 MR. WALLACE: Can you mark this, 2 please? 3 (Deposition Exhibit No. 6 was marked for 4 identification.) 5 Q. You've been handed what's been marked as 6 Exhibit 6; is that right? 7 And you recognize that as a 2015 8 instructions for use, correct? 9 A. Yes. 10 Q. And if you look to page 5 -- actually, pages 11 4 and 5, you'll see that under "adverse reactions," 12 "Acute and/or chronic pain" is now listed, right, 13 on page 5? 14 A. Yes. 15 Q. And that was not in the prior instructions 16 for use, right? 17 A. That's correct. 18 Q. And the chronic pain is different from 19 transitory pain, right? 20 A. Yes. 21 Q. And "Pain with intercourse," which in some 22 patients may not resolve, is listed in the 2015 23 IFU, but not in the prior IFUs, correct? 24 A. That's correct.</p>	<p style="text-align: right;">Page 125</p> <p>1 A. Because it doesn't degrade. 2 Q. So you disagree with Ethicon? 3 A. I do. 4 Q. And you would agree with me that there are 5 some very smart people at Ethicon? 6 A. There are. 7 Q. And you consider them your partners in 8 healthcare? 9 A. My partners in healthcare -- 10 Q. That's what you said earlier. 11 A. Sure. They're my partners in healthcare. 12 Q. And you expect them to give you accurate 13 information? 14 A. Right. When it's pertinent. 15 Q. And you would agree with me that 16 polypropylene mesh can chemically degrade? 17 A. No. I think it's conflicting. I certainly 18 know that your experts have data that states that 19 it may, and I can show you data that states that it 20 doesn't. 21 Q. You don't recall saying that it's possible 22 that polypropylene mesh can degrade? 23 A. I don't believe that it can have any 24 significant degradation. Certainly, mesh can</p>

<p style="text-align: right;">Page 126</p> <p>1 change.</p> <p>2 Q. Let's change the questioning so I don't have</p> <p>3 to ask you 20 questions, and we're not arguing</p> <p>4 about it.</p> <p>5 I'm going to ask you a more basic question.</p> <p>6 Putting aside whether you believe it has clinical</p> <p>7 relevance, do you believe that mesh can chemically</p> <p>8 degrade?</p> <p>9 A. I think mesh can degrade. I don't know that</p> <p>10 it can degrade chemically.</p> <p>11 Q. In any event, you believe that mesh can</p> <p>12 degrade, but it is also your opinion that that has</p> <p>13 no clinical relevance?</p> <p>14 A. Yes.</p> <p>15 Q. So you disagree with any Ethicon documents</p> <p>16 or any literature anywhere that suggests that</p> <p>17 degradation can cause pain in a person with mesh?</p> <p>18 MS. ROBINSON: Object to form.</p> <p>19 A. I'd have to see those documents in specific</p> <p>20 of what you're referring to.</p> <p>21 Q. Well, why haven't you looked at them?</p> <p>22 They've been provided to you by Ethicon.</p> <p>23 A. I've looked at material that I think is</p> <p>24 pertinent for each case.</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. Would it surprise you to know that that was</p> <p>2 investigated by Ethicon?</p> <p>3 A. I'm sure that they investigated a lot of</p> <p>4 things.</p> <p>5 Q. Do you believe that those specific effects</p> <p>6 of polypropylene degradation on erosion rates is</p> <p>7 known?</p> <p>8 A. I don't think it's known completely, no.</p> <p>9 Q. Do you agree with Ethicon if it said</p> <p>10 degradation is a process which initiates after a</p> <p>11 few days postimplant?</p> <p>12 A. No.</p> <p>13 Q. Have you seen any documents that conclude</p> <p>14 that, any animal studies, for example?</p> <p>15 A. That degradation occurs postimplant? There</p> <p>16 have been studies of dogs, there's some studies --</p> <p>17 there's animal studies that people have looked at.</p> <p>18 Q. Anything else?</p> <p>19 A. There have been some mesh removal studies,</p> <p>20 but I don't think that there are -- even the ones</p> <p>21 that your own experts cite are not conclusive in</p> <p>22 saying that there truly is degradation.</p> <p>23 Q. You don't know what additives are in the</p> <p>24 mesh, right?</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Well, you're giving a general opinion about</p> <p>2 the TVT, right?</p> <p>3 A. I'm giving a general opinion about the TVT,</p> <p>4 yes.</p> <p>5 Q. And you agree with me that there are people</p> <p>6 that have opined for Plaintiffs that mesh degrades</p> <p>7 and has clinical relevance?</p> <p>8 A. They believe that it does, yes.</p> <p>9 Q. And you're aware of case reports, for</p> <p>10 example, that demonstrate that the TVT is often</p> <p>11 taken out in pieces?</p> <p>12 A. Yes.</p> <p>13 Q. Yet is it still your opinion, knowing all</p> <p>14 of that, that you didn't think it was relevant to</p> <p>15 review degradation documents?</p> <p>16 A. I didn't say I didn't review degradation</p> <p>17 documents. What I'm telling you is that I don't</p> <p>18 believe that the information that your experts</p> <p>19 suggest is clinically relevant, and I have the</p> <p>20 documentation that believes otherwise.</p> <p>21 Q. Did you see any documents where Ethicon</p> <p>22 believed that degradation might affect erosion</p> <p>23 rates?</p> <p>24 A. No. I don't know of that.</p>	<p style="text-align: right;">Page 129</p> <p>1 A. No.</p> <p>2 Q. And you haven't undertaken an investigation</p> <p>3 to understand the process of degradation, right?</p> <p>4 A. I've taken an effort to understand the</p> <p>5 process, yes.</p> <p>6 Q. What is it?</p> <p>7 A. What is what process?</p> <p>8 Q. Well, you've said you've undertaken an</p> <p>9 effort to understand the process, so why don't you</p> <p>10 tell me what the process is.</p> <p>11 A. Degradation would imply that there's</p> <p>12 breakdown of mesh fibers, okay, and that could be</p> <p>13 visualized on a specimen. So, certainly, you'd have</p> <p>14 to remove mesh to look at the fibers and see if</p> <p>15 that were the case. The problems with that is that</p> <p>16 studies that are often quoted were removed to</p> <p>17 patients who have had pain or problems or</p> <p>18 infection, so we don't know what happens in mesh</p> <p>19 that's not removed in normal people. So that's</p> <p>20 certainly one of the problems.</p> <p>21 The other problem is that even within those</p> <p>22 studies, the type of reactions that occur are not</p> <p>23 well understood or supported. Further, the tissue</p> <p>24 that you're removing, you're not just removing</p>

<p style="text-align: right;">Page 130</p> <p>1 mesh; you're removing tissue with the mesh, so 2 pulling it, stretching it, changing its 3 configuration is going to change what that mesh 4 looks like under the microscope. 5 Further, looking at things like formalin and 6 how that has been used, there have been studies 7 that show that formalin may cause degradation, but 8 there are others that specimens were preserved with 9 formalin that showed no change in it, so. . . 10 Q. What are the studies that show formalin 11 causes degradation? 12 A. Let me take a minute. I don't remember 13 the specific study that showed that. I do 14 remember reading that. But in some of the ones I 15 looked at for degradation, there was no formalin 16 effect. I think it's controversial. In a study by 17 Woodruff, which looked at these meshes and also 18 looked at biological grafts, these implants were 19 actually placed in formalin. 20 Q. Okay. But I've asked you to explain the 21 process as you understand it. Can you tell me 22 anything chemically about the process of 23 degradation? 24 A. Well, it may relate to oxidizers. It may</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. You've been handed a document that's been 2 marked as Exhibit 7. Do you recognize it? 3 A. Yes. 4 Q. If you look at the bottom, you'll see the 5 statement that "the safety and effectiveness of 6 multi-incision slings is well-established in 7 clinical trials that followed patients for up to 8 one year." 9 Do you see that? The very bottom of the 10 first page? 11 A. Yes. 12 Q. Is this what you give your patients? 13 A. I don't give them that, no. 14 Q. You referenced earlier, though, a statement? 15 A. Yes. 16 Q. About the position statement that you 17 provide to your patients. 18 What do you mean by that? 19 A. With information from the position 20 statement, which is included further here, which 21 show the justifications. I provide them with the 22 justifications. 23 Q. Okay. So in other words, you took the 24 justifications on page 2, which provide the reasons</p>
<p style="text-align: right;">Page 131</p> <p>1 relate to bacteria that theoretically could do 2 that, although that's not clearly proven. Peroxide 3 may have an effect on that as well, but that's not 4 entirely clear. And if that is -- and if it does 5 occur, it doesn't have any clinical significance. 6 Q. But you agree with me that there are 7 documents and literature that show degradation in a 8 mesh, a transvaginal mesh that has been removed for 9 pain? 10 A. There are documents that show that. 11 Q. There are -- there's literature that shows 12 that, too? 13 A. There are documents that show that. 14 Q. And just so we're on the same page, 15 documents also means literature in your answer, 16 correct? 17 A. They're papers. They're papers. 18 Q. Peer-reviewed literature? 19 A. Yes. 20 Q. Thank you. You've seen the AUGS and SUFU 21 statement, right? 22 A. Yes. 23 (Deposition Exhibit No. 7 was marked 24 for identification)</p>	<p style="text-align: right;">Page 133</p> <p>1 why polypropylene mesh should be used and give it 2 to your patients? 3 A. I discuss each of these with them, yes. 4 Q. When you say "each of these," there are four 5 reasons? 6 A. Right. 7 Q. Do you believe you're an advocate for the 8 use of mesh? 9 A. I am. 10 Q. And so in providing this to your patients 11 who may be considering this procedure, you're being 12 an advocate for mesh? 13 A. Yes. 14 Q. And would you agree with me that showing the 15 safety and effectiveness of a product up to one 16 year is not a long-term safety study? 17 A. That's correct. 18 Q. And would you agree with me that every one 19 of the authors that are listed on Exhibit 7 have 20 been paid by industry? 21 A. In what sense have been paid by industry? 22 Q. Well, you know who Dennis Miller is, right? 23 A. Sure. 24 Q. Who is he?</p>

<p style="text-align: right;">Page 134</p> <p>1 A. He's on Saturday Night Live.</p> <p>2 Q. Who else is he?</p> <p>3 A. Actually, I don't know Dennis Miller.</p> <p>4 Q. You don't? Do you know if he has anything</p> <p>5 to do with mesh?</p> <p>6 A. I don't know, no.</p> <p>7 Q. So wouldn't you want to know if those people</p> <p>8 -- I mean, we talked about bias earlier?</p> <p>9 A. Right.</p> <p>10 Q. Do you think that if somebody was given</p> <p>11 millions of dollars as a result of mesh, do you</p> <p>12 think that that might affect their opinion?</p> <p>13 A. It might.</p> <p>14 Q. Wouldn't you want to know, at least,</p> <p>15 wouldn't you want it to be disclosed?</p> <p>16 A. Well, at the time that these positions</p> <p>17 statements have come about, this is 2014, so we've</p> <p>18 all had disclosures of each of us through the AUA</p> <p>19 and through AUGS for members. You know, we have</p> <p>20 disclosures that we have to put on our Web site, so</p> <p>21 I would expect that these people, if they are</p> <p>22 getting funds, that they are disclosed in their</p> <p>23 industry relations.</p> <p>24 Q. And it wouldn't surprise you to learn that</p>	<p style="text-align: right;">Page 136</p> <p>1 A. Yes.</p> <p>2 Q. You recognize those as people who are</p> <p>3 pretty high up at Ethicon?</p> <p>4 A. No. I don't know any of those names.</p> <p>5 Q. You don't?</p> <p>6 A. No.</p> <p>7 Q. Do you know anyone within Ethicon?</p> <p>8 A. No.</p> <p>9 Q. Have you as a result of being hired by</p> <p>10 Ethicon taken it upon yourself to talk to any</p> <p>11 employees of Ethicon?</p> <p>12 A. No.</p> <p>13 Q. You've had the opportunity to, didn't you?</p> <p>14 A. I'm sure I could have.</p> <p>15 Q. Wouldn't you, if you came across -- we</p> <p>16 talked earlier about the fact that you've seen</p> <p>17 documents that say particle loss is one of the</p> <p>18 reasons for a laser-cut mesh.</p> <p>19 Wouldn't you want to know more about that</p> <p>20 and what Ethicon concluded internally about that</p> <p>21 issue?</p> <p>22 A. If Ethicon had issues that were clinically</p> <p>23 relevant, they would be brought to all of us as</p> <p>24 clinicians, since we're users of the product. The</p>
<p style="text-align: right;">Page 135</p> <p>1 every single one of them are connected to the mesh</p> <p>2 industry in some way, right?</p> <p>3 A. It wouldn't surprise me, no.</p> <p>4 MR. WALLACE: Please mark this one.</p> <p>5 (Deposition Exhibit No. 8 was marked for</p> <p>6 identification.)</p> <p>7 Q. Can you look at Exhibit 8, please. Do you</p> <p>8 recognize it?</p> <p>9 A. I do not, no.</p> <p>10 Q. Have you seen it before?</p> <p>11 A. I have not.</p> <p>12 Q. Do you know whether or not it's included in</p> <p>13 your reliance list?</p> <p>14 A. I don't believe that it is. I don't recall</p> <p>15 seeing this document in this form in this e-mail.</p> <p>16 Q. Have you looked at every single document on</p> <p>17 your reliance list?</p> <p>18 A. I've looked at the vast majority of them,</p> <p>19 yes, but not each and every one of them. They're</p> <p>20 there for me so I can look at them as I need to.</p> <p>21 Q. You would agree with me, if you'll look at</p> <p>22 the middle of the way down the page, you'll</p> <p>23 recognize some of the names. Dan Lamont, Gene</p> <p>24 Kammerer. Do you see those names?</p>	<p style="text-align: right;">Page 137</p> <p>1 field team would come out to us -- the people would</p> <p>2 come to us, if they were clinically relevant. The</p> <p>3 reason they haven't is because it's not clinically</p> <p>4 relevant.</p> <p>5 Q. Well, look at the middle of the page. It</p> <p>6 says, "Particle loss is the reason why TVT wants to</p> <p>7 use laser-cut mesh to eliminate particle loss</p> <p>8 (which is critical to quality)."</p> <p>9 Do you see that?</p> <p>10 A. I do.</p> <p>11 Q. Do you agree with that statement?</p> <p>12 A. I've not seen that as an issue, okay? I've</p> <p>13 also looked at mesh as it comes out of the package</p> <p>14 from the very beginning. I've not seen any -- even</p> <p>15 any threads that are lost off of any mesh over the</p> <p>16 years as we take it out and check its expiration</p> <p>17 date and other opinion of it. So to me, I don't</p> <p>18 see any difference between laser-cut and</p> <p>19 mechanical-cut mesh.</p> <p>20 Q. Have you seen any studies that conclude</p> <p>21 otherwise?</p> <p>22 A. No.</p> <p>23 Q. You haven't?</p> <p>24 A. No.</p>

<p style="text-align: right;">Page 138</p> <p>1 Q. Have you seen any documents where the -- one</p> <p>2 of the coinventors of the TVT product believes</p> <p>3 that they won't use laser-cut mesh?</p> <p>4 A. No.</p> <p>5 Q. You haven't seen that?</p> <p>6 A. No.</p> <p>7 Q. Wouldn't that affect your opinion?</p> <p>8 A. No.</p> <p>9 Q. Why not?</p> <p>10 A. Because I have 15 years of opinion, and as I</p> <p>11 told you, I didn't know until 2007 that there was a</p> <p>12 change, that there was any difference between these</p> <p>13 two, because it has no clinical effect in our</p> <p>14 practice. It did not change any of the problems,</p> <p>15 or. . .</p> <p>16 Q. And that's solely based upon your own</p> <p>17 observations, right?</p> <p>18 A. Well, it's also been based upon</p> <p>19 presentations at meetings. I have not heard any</p> <p>20 discussion about this difference until this has</p> <p>21 been brought up most recently through these</p> <p>22 processes.</p> <p>23 Q. Have you seen any documents that conclude</p> <p>24 that the TVT could curl and rope, thereby reducing</p>	<p style="text-align: right;">Page 140</p> <p>1 you the be-all-end-all on that, wouldn't you agree?</p> <p>2 A. That's right.</p> <p>3 Q. So -- okay. So fair enough. You just don't</p> <p>4 consider Ethicon documents in that regard one way</p> <p>5 or another to support your opinion?</p> <p>6 A. These have no effect on my opinion</p> <p>7 whatsoever.</p> <p>8 Q. And you're just -- in other words, you just,</p> <p>9 because of your own experience, you're just not</p> <p>10 going to consider them?</p> <p>11 A. I don't have -- no.</p> <p>12 MS. ROBINSON: Object to form.</p> <p>13 A. I don't need to consider them.</p> <p>14 Q. Even if they disagree with your viewpoint?</p> <p>15 MS. ROBINSON: Object to form. Asked</p> <p>16 and answered.</p> <p>17 A. The way this is written and the way this is</p> <p>18 theorized can apply just as easily to</p> <p>19 mechanically-cut mesh or the laser-cut mesh. The</p> <p>20 issue with retention can be exactly the same.</p> <p>21 If it's going to cause retention, okay? And the</p> <p>22 issue with roping or curling would be on the ends</p> <p>23 of it, if it weren't placed in a tension-free</p> <p>24 fashion and it weren't evaluated carefully upon</p>
<p style="text-align: right;">Page 139</p> <p>1 the surface area of the mesh under the urethra and</p> <p>2 increasing the pressure in that area?</p> <p>3 A. No.</p> <p>4 (Deposition Exhibit No. 9 was marked for</p> <p>5 identification.)</p> <p>6 Q. Again, wouldn't you want to know that</p> <p>7 information if Ethicon had it?</p> <p>8 A. Unless it's clinically relevant, I don't</p> <p>9 need to know this.</p> <p>10 Q. Well, isn't it clinically relevant if the</p> <p>11 mesh can curl and rope and increase pressure under</p> <p>12 the urethra and cause pain in that area?</p> <p>13 A. I haven't opined to you that this is the</p> <p>14 case in all patients.</p> <p>15 Q. I said the issue is whether it can, right?</p> <p>16 A. Can mesh curl and rope? I've not seen that</p> <p>17 that's -- that that occurs clinically.</p> <p>18 Q. Wouldn't you want to know if you're talking</p> <p>19 about the safety and efficacy of a mesh device, a</p> <p>20 TVT, what Ethicon's own opinions are about that</p> <p>21 issue?</p> <p>22 A. Only if they're clinically relevant. I have</p> <p>23 my own -- after 15 years, I have my own opinions.</p> <p>24 Q. But your opinions doesn't necessarily make</p>	<p style="text-align: right;">Page 141</p> <p>1 completion of the procedure to know that it was --</p> <p>2 whether it was placed properly.</p> <p>3 And it also helps you -- it helps you, too,</p> <p>4 by looking where the pressure localizes --</p> <p>5 MS. ROBINSON: Not a question.</p> <p>6 MR. WALLACE: Can you mark that?</p> <p>7 (Deposition Exhibit No. 10 was marked for</p> <p>8 identification.)</p> <p>9 Q. Can you please look at Exhibit 10 and tell</p> <p>10 me if you have seen it before?</p> <p>11 A. I have not, no.</p> <p>12 Q. You've never seen the PA Consulting Group --</p> <p>13 A. No.</p> <p>14 Q. -- PowerPoint?</p> <p>15 A. Nope.</p> <p>16 Q. Do you realize that this PowerPoint</p> <p>17 concludes that mesh can degrade, and it talks about</p> <p>18 erosion in connection with degradation?</p> <p>19 MS. ROBINSON: He said he hasn't seen</p> <p>20 it.</p> <p>21 A. I haven't seen it, so if you want to talk --</p> <p>22 Q. Well, you may have been told about it?</p> <p>23 A. No. I've never been told about this</p> <p>24 document.</p>

<p style="text-align: right;">Page 142</p> <p>1 Q. Well, don't you want to know if information 2 that Ethicon has about degradation and its effect 3 on erosion, wouldn't you want to consider it, or 4 are you just going to sit here and say that your 5 15 years of experience is what matters? 6 A. I'm going to say that in my 15 years of 7 experience and in materials that I have reviewed 8 and seen, that I don't think there's any clinical 9 relevance to degradation and its relationship to 10 erosion. 11 Q. So in other words, if that document or other 12 documents like it conclude otherwise, you're just 13 not going to consider them? 14 A. I have to read this. I have not read this. 15 If you want to point me to a specific portion of 16 it -- 17 Q. Okay. I'm going to let you read it, and 18 please do, but just, my question is more basic than 19 that. 20 If -- assuming this document is contrary to 21 your opinion, you're just not going to consider it 22 because you're going to rely more on your 15 years 23 of experience, right? 24 A. I'm going to read it. I'll read anything</p>	<p style="text-align: right;">Page 144</p> <p>1 rates is not known"? 2 A. I think the degradation of polypropylene is 3 actually known. It's been studied. It doesn't 4 degrade. It's not been uniformly shown that it 5 degrades in all studies. 6 Q. Would you agree with the slide underneath it 7 that says "Mesh erosion is lower in polypropylene 8 meshes used in transabdominal surgery than in 9 transvaginal surgery"? 10 A. That's actually -- well, when you refer to 11 transabdominal surgery, what do you mean by that? 12 Q. I'm just asking you to look at the slide and 13 see whether or not you agree or disagree with the 14 statement. 15 A. Well, transabdominal surgery is very big. 16 Are we talking about, say, sacrospinous ligament 17 fixation? Are we talking about 18 abdominal sacrocolpopexy? What are we talking 19 about? 20 Q. So you just don't know? 21 A. Well, it doesn't say. It's a very vague 22 statement. And, actually, it is lower with 23 polypropylene meshes used in vaginal surgery than 24 transabdominal surgery.</p>
<p style="text-align: right;">Page 143</p> <p>1 that's provided to me, but that doesn't mean my 2 opinion will change. 3 Q. Go ahead. 4 A. Well, this is going to take me an hour to 5 read all these slides, so I would suggest in the 6 essence of time that you point to me what you want 7 me to look at specifically. 8 Q. Why don't you look at the second page, and 9 you'll see in the middle of the page it says "Mesh 10 erosion is complex, and the clinical studies do not 11 give a clear picture due to the diversity of 12 variables." 13 Do you agree with that statement? 14 A. That's true. 15 Q. Do you agree with the statement underneath 16 that, that says that "the causes of mesh erosion 17 are not well understood"? 18 A. They're not well understood, yes. 19 Q. Do you agree with the last bullet point in 20 that same slide in the middle of the page that says 21 "The situation is further complicated by known 22 factors, such as the propensity of polypropylene 23 (PP) to suffer degradation, and the specific 24 effects of polypropylene degradation on erosion</p>	<p style="text-align: right;">Page 145</p> <p>1 Q. Can you look at page 6, please, the bottom 2 slide on the left? Do you agree or disagree with 3 this statement that "polypropylene can suffer from 4 degradation following implant"? 5 A. I disagree. 6 Q. Look at the rest of the slide. Can you read 7 that? Look at the first bullet point. 8 I asked you earlier about animal studies in 9 connection with polypropylene. 10 A. Yes. 11 Q. And you'll see that the statement says that 12 there are animal studies that show that 13 degradation occurs a few days after post-implant, 14 or at least starts to occur. 15 Do you agree with that statement? 16 A. In that study, I mean, but that's an animal 17 study. It's not a human study. 18 Q. And what's the science behind your basis to 19 conclude that there's a difference? 20 A. Well, I can show you data. I can show you 21 the Woodruff study, which actually looked at 22 polypropylene mesh and shows that it didn't 23 degrade in meshes that were removed compared to 24 autologous slings that actually did show the</p>

<p style="text-align: right;">Page 146</p> <p>1 degradation.</p> <p>2 Q. Woodruff was an animal study?</p> <p>3 A. No, Woodruff was a human study.</p> <p>4 Q. And you're also aware of other studies that</p> <p>5 say that based upon explants that mesh degrades?</p> <p>6 A. As I said, it's not clear. I've mentioned</p> <p>7 to you and cited a very important study that shows</p> <p>8 that it doesn't degrade.</p> <p>9 Q. And you conversely also understand that</p> <p>10 there are studies that show that it does?</p> <p>11 A. Hence the reason why there's controversy.</p> <p>12 Q. And wouldn't you want to know what Ethicon</p> <p>13 has to say about that issue?</p> <p>14 A. If it were important, they would have told</p> <p>15 me a long time ago.</p> <p>16 Q. But you didn't see this document before</p> <p>17 today, did you?</p> <p>18 A. No. And it doesn't change my opinions now</p> <p>19 seeing the document.</p> <p>20 Q. Why?</p> <p>21 A. Why what?</p> <p>22 Q. Why doesn't it change your opinions?</p> <p>23 A. Because if there were a significant issue</p> <p>24 with this product that all physicians needed to</p>	<p style="text-align: right;">Page 148</p> <p>1 Hendrix matter. And I'm specifically referring</p> <p>2 to the general part of your report.</p> <p>3 What do you mean when you use the word</p> <p>4 "dense fibrosis" on page 8?</p> <p>5 A. Dense means thick. Fibrosis means scarring.</p> <p>6 So thick scar.</p> <p>7 Q. I'm trying to use a lot of "it's important</p> <p>8 to note" type of paragraphs, so I'm trying to</p> <p>9 figure out what you're really saying in this</p> <p>10 paragraph. Can you try to explain that to us?</p> <p>11 A. Yeah. And, actually, this is an</p> <p>12 interpretation via the "Discussion" section of the</p> <p>13 Wang paper, okay? And this -- Wang, et al. These</p> <p>14 are the authors stating that the inadequate</p> <p>15 vaginal tissue coverage during the operation, mesh</p> <p>16 rigidity, propensity for an injury at a nearby</p> <p>17 site, or localized inflammation is somewhat</p> <p>18 plausible. So, in other words, it's localized</p> <p>19 inflammation is what you're referring to now.</p> <p>20 In patients who have complete epithelia-</p> <p>21 lization of the mesh -- in other words, the vaginal</p> <p>22 wall is well healed underneath -- and then their</p> <p>23 mesh was removed for some other reason, like they</p> <p>24 wanted it removed or had some other procedure,</p>
<p style="text-align: right;">Page 147</p> <p>1 know about that was different from what they</p> <p>2 learned from their skills and training and</p> <p>3 education that was unique to this product and</p> <p>4 not any other one, they certainly would have told</p> <p>5 us information in a timely fashion.</p> <p>6 Q. And even though you agree with the part of</p> <p>7 the PowerPoint that I showed you that the concept</p> <p>8 of mesh erosion, for example, and the studies</p> <p>9 associated with it are complex and difficult to</p> <p>10 understand?</p> <p>11 A. Um-hmm. They're certainly complex, yes.</p> <p>12 Q. Well, isn't that the most common</p> <p>13 complication associated with mesh?</p> <p>14 A. Erosion?</p> <p>15 Q. Um-hmm.</p> <p>16 A. Actually, no, not that I see.</p> <p>17 Q. What are the most common complications?</p> <p>18 A. Most common complication that I see is</p> <p>19 voiding dysfunction, urgency and frequency,</p> <p>20 urge incontinence, pelvic pain. I actually see</p> <p>21 very few mesh extrusions, and that's well</p> <p>22 documented. The extrusion rate for vaginal mesh is</p> <p>23 less than 1 percent on average.</p> <p>24 Q. Please turn to page 8 of your report in the</p>	<p style="text-align: right;">Page 149</p> <p>1 that even in these patients who don't have issues,</p> <p>2 they have -- some of them have had a foreign body</p> <p>3 reaction, fibrosis, and perivascular mononuclear</p> <p>4 cell infiltrate, which means they had chronic</p> <p>5 inflammatory evidence.</p> <p>6 So the point is, the inflammation that is</p> <p>7 seen as a histologic reaction can be present in</p> <p>8 slings that have extruded, which they talked about</p> <p>9 earlier. Epithelialized, in other words, maybe</p> <p>10 they had an erosion, it was cut, and then the</p> <p>11 vaginal tissue healed, or it looked completely</p> <p>12 normal but they removed it for some other reason.</p> <p>13 That's what that paper means.</p> <p>14 Q. Look at page 9. And just for clarification,</p> <p>15 your report says three. You thought that maybe two</p> <p>16 patients that had mesh extrusion.</p> <p>17 You used the word "three" on page 9. Do you</p> <p>18 see that?</p> <p>19 A. Yeah.</p> <p>20 Q. Is it three or two?</p> <p>21 A. It might be three. Again, this is -- you</p> <p>22 know, off the top of my head.</p> <p>23 Q. Well, you want to be careful, right?</p> <p>24 A. Right.</p>

<p style="text-align: right;">Page 150</p> <p>1 Q. It was just off the top of your head; is 2 that what you said? 3 A. Yes. 4 Q. When you say "off the top of your head," 5 meaning, you believe, off the top of your head 6 there's been only three patients that you're aware 7 of? 8 A. That I'm aware of that had TVT mesh erosion, 9 yes. 10 Q. And why did you look at the mesh under a 11 magnifying glass? 12 A. Where are we seeing that? 13 Q. In that same paragraph. 14 A. Well, the thing when you have a lot of mesh 15 is -- and certainly, there's a lot of different 16 theories about what happens to mesh, looked at 17 pathologically, and, you know, I thought it would 18 be interesting to just look and see. Actually, 19 we're looking even with optical loupes to look 20 and see what happens. 21 Usually, we're doing it when we're putting 22 them in. So in other words, after we're finished, 23 I put on my loupes and just look and see how the 24 mesh lays. And I've not seen any differences or</p>	<p style="text-align: right;">Page 152</p> <p>1 contaminated field? 2 A. Contaminated in terms of what? Contaminated 3 in terms of infection or we also talked about 4 peroxides and other things? 5 Q. Sure. Let's just stay with peroxide. 6 A. Yes. 7 Q. And you would agree with me that where it 8 sits, it's exposed to fibroblasts and neutrophils 9 at points in time? 10 A. Let's go back to peroxidase, okay? Not all 11 bacteria secretes peroxidase. Not all 12 lactobacillus secretes peroxidase. And the 13 peroxidase levels -- peroxide levels change in 14 menopausal status with women. 15 Q. So all women are different? 16 A. So all women are different. 17 Q. So one woman might have more reactive 18 oxidative species than another? Or she might have 19 cells, for example, that secrete more peroxidase? 20 A. They might. But -- 21 Q. You would agree with me? 22 A. Yeah. But that's probably not clinically 23 relevant. 24 Q. Probably not?</p>
<p style="text-align: right;">Page 151</p> <p>1 any problems associated with it. 2 Q. You'd agree with me that there are peroxides 3 present in the vaginal tissues? 4 A. Vaginal tissues or. . . 5 Q. Or vaginal space. 6 A. That's two different things. Is it in the 7 vaginal space, i.e., the bacteria that are present 8 within the lumen of the vagina, yes. 9 Q. And that's actually the area in which the 10 TVT is? 11 A. No. 12 Q. Goes through? 13 A. No. 14 Q. You don't think so? 15 A. No. 16 Q. You don't think it's ever exposed to any 17 clean -- or contaminated area? 18 A. Well, the vagina always has bacteria, and we 19 know that in all surgeries that we do. But once 20 that area is closed and there's complete 21 epithelialization, there shouldn't be any type of 22 infection that occurs in these meshes. 23 Q. But there's a possibility that -- of how 24 this device is put in that it can be exposed to a</p>	<p style="text-align: right;">Page 153</p> <p>1 A. Probably not. 2 Q. In your opinion, based on what signs? 3 A. Based on just looking at degradation of mesh 4 that was studied. Just looking at mesh that was 5 removed. Looking at the Woodruff study, and 6 looking at there was no degradation in that group 7 that had TVT mesh removed. 8 Q. You would agree with me that there are some 9 women that are called high responders, right? 10 A. What is a high responder? 11 Q. Meaning that they might have a greater 12 inflammatory response than another woman because of 13 their status in life, just how they're made? 14 MS. ROBINSON: Object to form. 15 A. It may -- it's -- probably is not that as 16 their basis. They probably have an underlying 17 condition, an underlying inflammatory condition, 18 which is well known. Things like lupus and 19 rheumatoid arthritis and other things. But that 20 inflammation doesn't necessarily relate to what the 21 bacteria in the vaginal canal are doing. That 22 may just be their own immunogenicity. 23 Q. In other words, whether a woman secretes 24 more peroxidase than another, you don't believe</p>

<p style="text-align: right;">Page 154</p> <p>1 that that would have any clinical impact on their</p> <p>2 healing or the mesh?</p> <p>3 A. No. It shouldn't have an impact on that.</p> <p>4 And, furthermore, the issue with bacteria shouldn't</p> <p>5 have any effect on it either, because in meshes</p> <p>6 that were removed, even in Clavet's work, when he</p> <p>7 looked at that, he couldn't conclude that there was</p> <p>8 bacteria present, even in a patient with acute</p> <p>9 inflammation, in group one, no bacteria genesis was</p> <p>10 noted.</p> <p>11 MR. WALLACE: Can we go off for a</p> <p>12 minute?</p> <p>13 (Off the record 2:43 p.m.)</p> <p>14 (On the record at 2:45 p.m.)</p> <p>15 MR. WALLACE: I have no further</p> <p>16 questions.</p> <p>17 MS. ROBINSON: I have a couple</p> <p>18 follow-up.</p> <p>19 CROSS-EXAMINATION</p> <p>20 BY MS. ROBINSON:</p> <p>21 Q. Dr. Zaslaw, do you recall counsel's</p> <p>22 questions of you regarding whether you were an</p> <p>23 advocate for mesh?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 156</p> <p>1 products? Yes. Because without their products I</p> <p>2 wouldn't be able to do these surgeries.</p> <p>3 Q. And you believe it's important for you to be</p> <p>4 able to offer these products to your patients?</p> <p>5 A. Yes.</p> <p>6 Q. You were asked some questions by counsel</p> <p>7 earlier about warnings and whether you were an</p> <p>8 expert in warnings.</p> <p>9 Would you agree with me in this case that</p> <p>10 you've been asked to offer your opinion as to</p> <p>11 whether the information provided by Ethicon in its</p> <p>12 IFUs was sufficient for you as a physician and for</p> <p>13 physicians in general to use their product?</p> <p>14 A. I think the information there is sufficient</p> <p>15 to use.</p> <p>16 Q. But that's essentially what you've been</p> <p>17 asked to opine on; is that correct?</p> <p>18 A. Yes.</p> <p>19 Q. About how you and other physicians read IFUs</p> <p>20 and utilize them in your practice, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Now, he was asking you more questions about</p> <p>23 the technical requirements of what goes in the IFU</p> <p>24 as to drafting and regulatory requirements and</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. And you responded that you were; is that</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. And what are you -- what does that mean to</p> <p>5 you, being an advocate for mesh? What does that</p> <p>6 mean for you?</p> <p>7 A. It means that in my clinical experience of</p> <p>8 15 years, in my teaching to residents, as such,</p> <p>9 and review of the literature that this is a</p> <p>10 procedure that has worked well in my hands with</p> <p>11 long-term efficacy.</p> <p>12 Q. And as a result of that, when you counsel</p> <p>13 your patients and you talk to them about mesh, is</p> <p>14 this a product that you feel that you want to offer</p> <p>15 to them as a choice to use and help them with their</p> <p>16 stress urinary incontinence?</p> <p>17 A. I do, yes.</p> <p>18 Q. When you indicate that you're an advocate</p> <p>19 for mesh, does that correlate to being an advocate</p> <p>20 for industry?</p> <p>21 MR. WALLACE: Objection to form.</p> <p>22 A. I'm an advocate for mesh as a procedure. In</p> <p>23 my hands, it's worked and it's worked well.</p> <p>24 Do I support industry by using industry's</p>	<p style="text-align: right;">Page 157</p> <p>1 everything like that, correct?</p> <p>2 A. Yes.</p> <p>3 Q. You're not a regulatory expert, right?</p> <p>4 A. I am not.</p> <p>5 Q. And you're not holding yourself out to be</p> <p>6 one; is that correct?</p> <p>7 A. Not at all.</p> <p>8 Q. So with regard to the information for use,</p> <p>9 are the complications that you have seen in your</p> <p>10 practice consistent with the warnings listed in the</p> <p>11 "Adverse Reactions" section of the IFU, in</p> <p>12 particular, the exhibit from 2001?</p> <p>13 MR. WALLACE: Objection to form.</p> <p>14 A. It was sufficient, yes, but the other</p> <p>15 issues that had come in the other iterations were</p> <p>16 things that were already known to us. They were</p> <p>17 just included for other reasons.</p> <p>18 Q. Counsel asked you whether chronic pain was</p> <p>19 listed in the IFU in 2001, and it was not, correct?</p> <p>20 A. Right.</p> <p>21 Q. And you indicated, I believe, in your</p> <p>22 response that you didn't feel that it was necessary</p> <p>23 for chronic pain to be listed; is that correct?</p> <p>24 A. That's correct.</p>

<p style="text-align: right;">Page 158</p> <p>1 Q. And why is that?</p> <p>2 A. Because it's known to all surgeons who do</p> <p>3 any pelvic surgery that pain can result, and it</p> <p>4 could be chronic.</p> <p>5 Q. So if I understand your testimony, it's</p> <p>6 based on the fact that individuals using the</p> <p>7 product are surgeons who operate in the pelvic</p> <p>8 floor, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And those surgeons are aware that any</p> <p>11 surgery they do to correct stress urinary</p> <p>12 incontinence, a hysterectomy, or otherwise can</p> <p>13 result in having chronic pain, correct?</p> <p>14 A. Yes, it can.</p> <p>15 Q. And based on -- your testimony is based on</p> <p>16 your own practice, correct?</p> <p>17 A. Yes.</p> <p>18 Q. But you're also a teacher, correct?</p> <p>19 A. Yes.</p> <p>20 Q. Do you teach your students utilizing IFUs at</p> <p>21 times?</p> <p>22 A. We review for the first time when someone</p> <p>23 does a procedure, I show them the IFU. There's</p> <p>24 nice pictures in it, pictorials, and also the</p>	<p style="text-align: right;">Page 160</p> <p>1 questions concerning degradation and its effect</p> <p>2 on erosion and extrusion of mesh, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And he asked you a series of questions about</p> <p>5 whether Ethicon had shared with you certain</p> <p>6 documentation, studies, conclusions, and theories</p> <p>7 offered by its various company employees, correct?</p> <p>8 A. Yes.</p> <p>9 Q. You indicated that you're not -- that that</p> <p>10 kind of information isn't information that is</p> <p>11 information that's important to you in your</p> <p>12 practice; is that correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And to a jury, that may sound like, "Well,</p> <p>15 Dr. Zaslaw has his head in the sand. He just</p> <p>16 doesn't want to know anything."</p> <p>17 Would you agree with me that that's what</p> <p>18 it sounds like?</p> <p>19 MR. WALLACE: Objection to form.</p> <p>20 A. I know that if there were anything</p> <p>21 pertinent, internally, regarding this procedure</p> <p>22 that Ethicon would have let physicians know</p> <p>23 immediately. Okay?</p> <p>24 Q. So my question of you is with regard to</p>
<p style="text-align: right;">Page 159</p> <p>1 step-by-step aspect of the procedure so they can</p> <p>2 have something to take home and see what they've</p> <p>3 done.</p> <p>4 Q. And so the IFU is more than just a list of</p> <p>5 complications and adverse effects as counsel has</p> <p>6 discussed with you, correct?</p> <p>7 A. Right, yes.</p> <p>8 Q. And have you found the Ethicon's IFU with</p> <p>9 regard to the TVT and TVT-O products to have been</p> <p>10 adequate for describing the procedure, as well as</p> <p>11 the potential complications and risks of the</p> <p>12 procedure?</p> <p>13 A. Yes.</p> <p>14 Q. Have you ever expressed any concern about</p> <p>15 any complications that are not listed in the IFU?</p> <p>16 A. No.</p> <p>17 Q. When you have attended meetings of your</p> <p>18 colleagues, of other urogynecologists or other</p> <p>19 urologists or gynecologists, have they experienced</p> <p>20 or expressed concerns to you about warnings and</p> <p>21 complications that were not contained in the IFU</p> <p>22 unrelated to mesh litigation?</p> <p>23 A. No.</p> <p>24 Q. Counsel also asked you a laundry list of</p>	<p style="text-align: right;">Page 161</p> <p>1 degradation and that process.</p> <p>2 A. Right.</p> <p>3 Q. Degradation in and of itself, is it a</p> <p>4 complication?</p> <p>5 A. No, it's not a complication.</p> <p>6 Q. Does degradation have any impact in and of</p> <p>7 itself on the woman that you are treating?</p> <p>8 A. No.</p> <p>9 Q. So degradation insofar as it may be linked</p> <p>10 to mesh exposure or erosion, as counsel's been</p> <p>11 asking you about, do you have knowledge of that</p> <p>12 impact through the literature that you read, your</p> <p>13 experience, and association and communications with</p> <p>14 your colleagues?</p> <p>15 A. Right.</p> <p>16 Q. In other words, you know the mesh erosion</p> <p>17 and extrusion rates, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And you read about that in the literature</p> <p>20 every day?</p> <p>21 A. Yes.</p> <p>22 Q. And it's been written about since mesh was</p> <p>23 first used way back in --</p> <p>24 A. In 1998, or even before that with the other</p>

<p style="text-align: right;">Page 162</p> <p>1 meshes, the other procedures. Right.</p> <p>2 Q. Correct. To your knowledge, has degradation</p> <p>3 resulted in any new complication that was unknown</p> <p>4 to physicians who operate in the pelvic floor using</p> <p>5 mesh?</p> <p>6 A. No.</p> <p>7 MS. ROBINSON: That's all the questions</p> <p>8 I have.</p> <p>9 REDIRECT EXAMINATION</p> <p>10 BY MR. WALLACE:</p> <p>11 Q. Would you agree with me that a woman said --</p> <p>12 who now has chronic pain that has been associated</p> <p>13 with a TVT, who says that she was never told that</p> <p>14 she might have chronic pain, that's an unfortunate</p> <p>15 event, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And you would agree with me that her</p> <p>18 physician, even going all the way back to 2001,</p> <p>19 should have told her about that, just like you've</p> <p>20 told your patients?</p> <p>21 A. Physicians who do any pelvic surgery</p> <p>22 should warn the patient that chronic pain can</p> <p>23 happen from any procedure.</p> <p>24 Q. And specifically from the TVT procedure?</p>	<p style="text-align: right;">Page 164</p> <p>1 CERTIFICATE</p> <p>2 STATE OF WEST VIRGINIA)</p> <p>3 I, Faye Ann Lehman, a Commissioner in</p> <p>4 and for the State of West Virginia, do hereby</p> <p>5 certify that before me personally appeared STANLEY</p> <p>6 ZASLAU, M.D., who was by me first duly cautioned</p> <p>7 and sworn to testify to the truth, the whole truth</p> <p>8 and nothing but the truth in the taking of his oral</p> <p>9 deposition in the cause aforesaid; that the</p> <p>10 testimony then given by him as above set forth is a</p> <p>11 true record of the testimony given by the witness,</p> <p>12 and was reduced to stenotype by me in the presence</p> <p>13 of said witness and afterwards transcribed upon a</p> <p>14 computer.</p> <p>15 I do further certify that this deposition</p> <p>16 was taken at the time and place specified in the</p> <p>17 foregoing caption and was completed without</p> <p>18 adjournment.</p> <p>19 I do further certify that I am not a</p> <p>20 relative of or counsel or attorney for any party</p> <p>21 hereto,</p> <p>22 IN WITNESS WHEREOF, I have hereunto set</p> <p>23 my hand and affixed my seal of office on this 22nd</p> <p>24 day of March, 2016.</p> <p>The foregoing certification does not</p> <p>apply to any reproduction of this transcript in any</p> <p>respect unless under the direct control and/or</p> <p>supervision of the certifying reporter.</p> <p>_____ Faye Ann Lehman, Commissioner My Commission Expires May 20, 2020</p>
<p style="text-align: right;">Page 163</p> <p>1 A. From any incontinence procedure.</p> <p>2 Q. Right. And specifically from the TVT</p> <p>3 procedure, because I'm talking about the TVT?</p> <p>4 A. Right. Then yes.</p> <p>5 Q. Okay. And -- but you would also agree with</p> <p>6 me that a physician is entitled to rely on the</p> <p>7 instructions for use?</p> <p>8 A. In part. And the remainder is from their</p> <p>9 clinical experience and education and teaching,</p> <p>10 coursework, lectures, meetings.</p> <p>11 MR. WALLACE: I have no further</p> <p>12 questions.</p> <p>13 MS. ROBINSON: I have nothing further.</p> <p>14 Thank you.</p> <p>15 (At 2:54 p.m., the deposition concluded</p> <p>16 and signature was not waived.)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 165</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4</p> <p>5 PAGE LINE CHANGE</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p>

<div style="text-align: right;">Page 166</div> <div>1 ACKNOWLEDGMENT OF DEPONENT</div> <div>2</div> <div>3 I, _____, do</div> <div>4 hereby certify that I have read the</div> <div>5 foregoing pages, and that the same is</div> <div>6 a correct transcription of the answers</div> <div>7 given by me to the questions therein</div> <div>8 propounded, except for the corrections or</div> <div>9 changes in form or substance, if any,</div> <div>10 noted in the attached Errata Sheet.</div> <div>11</div> <div>12</div> <div>13 _____</div> <div>14 STANLEY ZASLAU, M.D. DATE</div> <div>15</div> <div>16</div> <div>17 Subscribed and sworn</div> <div>18 to before me this</div> <div>19 _____ day of _____, 20____.</div> <div>20 My commission expires: _____</div> <div>21</div> <div>22 _____</div> <div>23 Notary Public</div> <div>24</div>	

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